RetCam Shuttle

Wide-Field Digital Imaging System

User Manual

PN 20-000106 Rev. C
For use with
software version 4.1

Clarity
medical systems

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1 Introduction

The RetCam Shuttle from Clarity Medical Systems is an integrated, mobile wide-field digital imaging system. Clarity designed the RetCam Shuttle to be maneuverable in constrained areas and for total system transport within and between hospitals and clinics. The RetCam Shuttle is made to have site awareness, which means it is made to be aware of the physical location where it is being operated. Thus, it prompts you at start-up to identify the operating location and it identifies saved data according to location. It also offers networkability, to support data transfer to and from the system and the multiple locations where it may be used.

With the exception of a fluorescein angiography light source and attached printers, the RetCam Shuttle offers the same basic functionality as the RetCam II, the leading choice for wide-field pediatric retinal imaging. The imaging system, including camera and lens choices, is identical, as are the image viewing, processing and other utilities.

The system is designed for easy operation by either a clinician or trained staff members. Using the integrated notebook computer, you have point-and-click access to all functions via the system software. You can use the RetCam Shuttle to quickly capture, display, process, and transfer high resolution digital images.

Indications for Use

For general ophthalmic imaging, including retinal, corneal, and external.

Purpose and Organization of this Manual

This manual serves as a usage and reference guide for the RetCam Shuttle. It first provides introductory and safety information (Chapter 1 Introduction), and then system level information (Chapter 2 System Functions, page 26). It is then organized according to the expected sequence of use, as follows:

- Chapter 3 Start, Patient Select, New Session, page 38
- Chapter 4 Review and Compare Images, page 57
- Chapter 5 Process Images, page 64
- Chapter 6 Data Transfer, page 72
- Chapter 7 Utilities, page 95

Succeeding chapters cover Maintenance and Support, Specifications and License Agreements. Finally, this manual provides an Index to assist you with finding desired information.

The Introduction covers the following topics:

- System Hardware, below

- Software Overview: RetCam Shuttle Screens and Functions, page 14
- Storage, page 16
- Transport, page 16
- Electrical Safety Information, page 18
- FDA (USA) Notices, page 22
- Important User Safety Notices, page 22
- Labels and Symbols, page 23

System Hardware

The RetCam Shuttle system consists of modules mounted in a stable, high quality integrated mobile cart for easy, safe transport from one location to another. The four casters allow for easy maneuverability and positioning. Figure 1 and Figure 2 below illustrate the system hardware.

WARNING: Unauthorized modifications or additions to the software or hardware of the system will void the warranty and could adversely affect the system function.

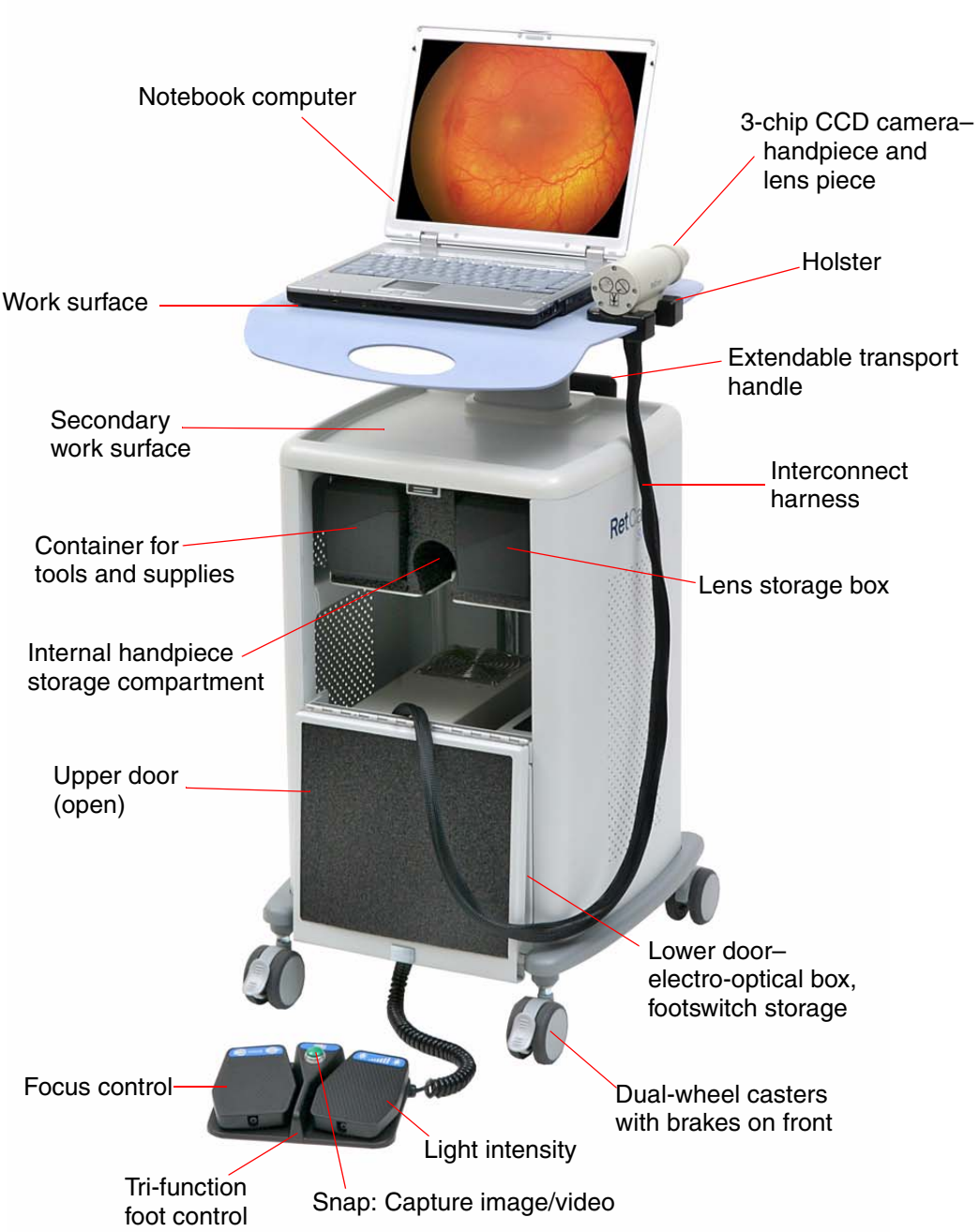


Figure 1 RetCam Shuttle Imaging System

Hardware Components

- **Notebook Computer:** Pre-loaded with RetCam Shuttle system software, it comes as part of the system. Offers a large LCD display for real-time video and still imaging, image processing and data transfer. A Pentium-based system running Windows® XP Professional, it includes a DVD/R/RW drive, integrated network adapter and USB ports.

☞ **Note: For information on the rechargeable battery of the notebook computer, please see the manufacturer's user manual found on the RetCam Shuttle CD.**

- **Handpiece:** Contains the 3-chip CCD camera. Lightweight and easy to position, it has a long cable for easy reach. Use with 3 changeable lens pieces. (See details in Figure 2 and Figure 3.)

☞ **Note: Always return the handpiece to the holster on the work surface when not imaging. The handpiece cable can be draped over the transport handle, but do not wrap it tightly or damage to the fiber optic may result.**

- **Handpiece Interconnect Harness:** Comprises three separate cables: the lamp (fiber optic) cable for subject illumination, the camera controller cable, and the focus motor cable.
- **Electro-Optical (EO) Box:** Contains the CCD camera control unit, a halogen illumination lamp, and the control circuitry for light intensity, camera focus, image capture and system logic. The front panel has outlets for computer power (DC/DC power) and USB video, the footswitch and the three interconnect camera handpiece harness cables. (See The Electro-Optical Box on page 32 for more details.)
- **Footswitch:** A rocker pedal on each side, and a push button in the middle.
  - **Focus control—left pedal**: Rock to the left to focus closer, to the right to focus more distant.
  - **Light intensity—right pedal:** Rock to the left to decrease intensity, to the right to increase intensity.
  - **Snap switch—central push button:** Press to capture and store the current still image, or in video mode, to start and stop recording.
- **Storage Compartment(s):** Particularly useful for safe transport, compartments inside the upper cart door provide storage for the handpiece, the lens pieces, and a container for tools and supplies. Inside the lower door on the right is a compartment for the footswitch.
- **Transport Handle:** Extends to tilt and roll the cart to another location.

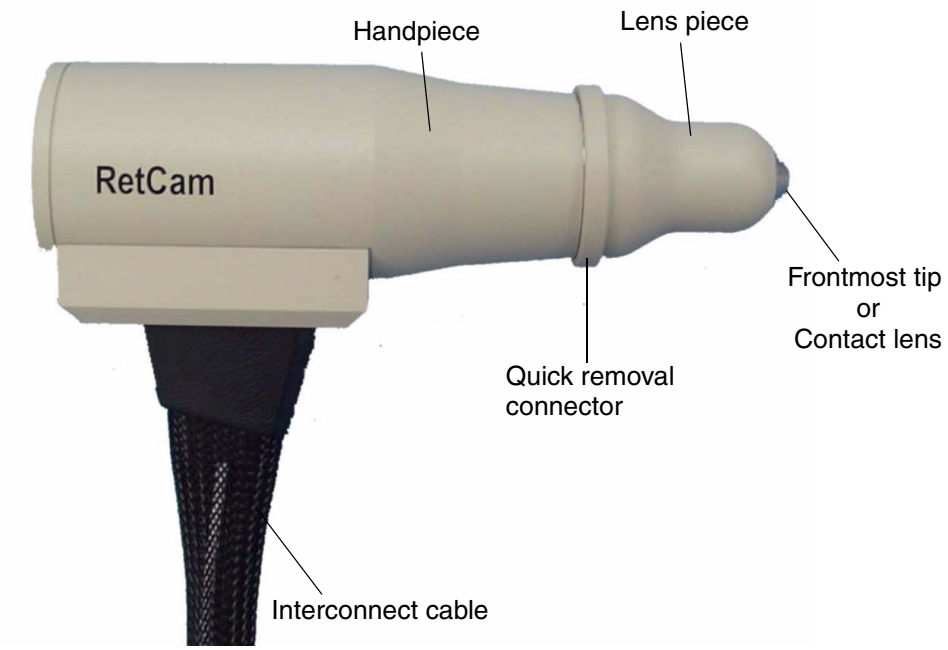


Figure 2 Handpiece and Lens Piece

Figure 3 Lens Piece Selection

Lens Model	Application	Common Field of View
D1300	ROP & Anterior Segment	130 Degrees
E800	High Contrast Children's & Adults	80 Degrees
PL100	Portrait Lens	N/A
C300	High Magnification	30 Degrees

Software Overview: RetCam Shuttle Screens and Functions

This section provides an outline of the primary functions available with the RetCam Shuttle. The system provides access to each major function on a separate screen. The same tabs present at the top of all screens provide easy navigation from one function to another. Just click on the tab to access the screen. Alternatively, you can access each screen using the function keys F1 through F8 on your keyboard, which give access to screens in the same left to right order as the on-screen tabs.

Function Key	Target Screen
F1	Patient Select
F2	History
F3	New Session
F4	Review
F5	Compare
F6	Process
F7	Transfer
F8	Utilities

Splash Screen

Click **Start Using the RetCam Shuttle**, which opens to the Patient Select screen

Patient Select Screen, F1

View and search patient list, add and edit patient records.

1. Select data source: resident patients or data saved on other media
2. For resident patients, manage patient information
   - Add new patients
   - Edit patient data
3. Add patient data from other media to resident data
4. Search for patients by name, ID, doctor, pathology, or date last seen

History Screen, F2

Displays detailed history for a selected patient, with session information for OD (right eye) and OS (left eye).

1. View patient history

New Session Screen, F3

Live imaging session for the selected patient.

1. Save still images
2. Record video

3. Save still images from recorded video
4. Erase video
5. Enter session notes

Review Screen, F4

View all images taken for the selected patient.

1. Navigate through images for all sessions
2. Display and enter session notes
3. Hide or skip over image
4. Flag image

Compare Screen, F5

Compare two images side by side. Compare any two images for the same patient from any session, or compare images from different patients.

1. Compare hidden images
2. Compare flagged images
3. Print 2 images

Process Screen, F6

Apply image processing functions.

1. Rotate 180º
2. Annotate images
3. Adjust Brightness, Contrast, Red, Green, Blue
4. Save and export files as BMP, JPEG, or PNG.
5. Open BMP, JPEG, or PNG file
6. Display and enter session notes

Transfer Screen, F7

Transfer images to any accessible location. May be used to share or back up images.

1. Select individual image(s) for transfer
2. Select multiple images for transfer
   - Visible Items
   - Flagged Items
   - Entire Session
   - Entire Patient
   - Today's Items

- Last 7 Days' Items
- Search Result

3. Select transfer destination and folder options
4. Batch transfer as MLX file (RetCam image file) for RetCam viewing
5. Batch transfer as BMP, JPEG, or PNG, with or without patient data.
6. Annotate and batch transfer BMP, JPEG, or PNG files
7. Transfer patient data as CSV, XML or Text files

Utilities Screen, F8

1. Change system institution name and department
2. View software version information
3. Access Windows Network Connections dialog
4. Adjust speaker volume
5. Adjust system date/time
6. Select default printer(s) for images and reports
7. Manage installed removable media
8. Enable or disable Auto-Indexing option

Software Note: Reboot to Refresh Drop-Lists

For several kinds of drop-lists, you must reboot the system to display new items you add. For example, when you add a new doctor's name, a new pathology or a new patient's name, the new items will not appear in the applicable drop-lists until you reboot the system.

Figure 4 Shuttle with all items stowed

Storage

For storage of the system when not in use, disconnect the power cord and store it inside the cart. Stow the handpiece in its compartment behind the upper door and the footswitch in its compartment behind the lower door. Remove all loose objects from the work surfaces. Close the notebook computer and consider removing it to a secure location. Wipe the surfaces with a soft cloth. Apply the brakes to the front casters to keep it in place.

Transport

The system is designed to be transportable, both within and between hospitals, clinics and offices.

☞ **Note: The system has no internal power supply (no battery) to support image acquisition while disconnected from a wall outlet. (The notebook computer can operate using its own battery.)**

To relocate the system within a building:

1. Power down the system through the software by clicking the **Shutdown** button, which can be found at upper right on most screens.
2. Switch off mains power on the back of the unit. Unplug the power cord from the wall outlet and drape it over the transport handle.
3. Secure the camera handpiece in its external holster on the work surface or internally. Drape the handpiece cable over the transport handle or place the excess inside the upper storage compartment.
4. Release the front caster brakes.

Now you can gently roll the system on all four wheels to the new location. If the floor is an uneven or tiled surface, move the system slowly to reduce damage from excessive vibration. Once in the new position, apply the front caster brakes, plug in the power cord and restart the system.

To transport the system to another location:

1. Power down the system through the software by clicking the **Shutdown** button, which can be found at upper right on most screens.
2. Switch off mains power on the back of the unit. Unplug the power cord from the wall outlet and drape it over the transport handle. If you wish, you can detach it from the rear of the system and place it inside the cart.
3. Remove the lens and store it in the lens box and secure the camera handpiece and the footswitch in their storage compartments inside the cart. The camera cable also fits inside the upper and lower storage compartments.

Figure 5 Transporting the Shuttle

4. Remove the notebook computer from the work surface and carry it separately.

5. Make sure the cart doors are closed. Release the front caster brakes.

6. Extend the transport handle upward and use it to tilt the cart and roll it to a vehicle for transport.

Inside the vehicle, you may lay the RetCam Shuttle on the slider bars on its back side, with the two front compartment doors facing upward. You may also place the Shuttle system upright and apply the front caster brakes. It may require more than one person to lift and position the system properly in the vehicle. Do not place the system on its work surface (not upside down), nor on either side with the front compartment doors facing sideways.

When you unload and place the device at its new work location, apply the caster brakes, plug in the power cord, unpack the handpiece and footswitch, connect and power on the notebook computer.

Electrical Safety Information

The RetCam Shuttle System has been designed, inspected and tested to comply with the safety requirements of IEC60601-1 with respect to fire, shock and mechanical hazards only if used as intended.

Model: RetCam Shuttle
Manufactured by Clarity Medical Systems, Inc.
dba Massie Laboratories, Inc.
Pleasanton, CA
Made in USA

Class 1 Type BF Electrical Equipment

Rated for Continuous Operation

IEC 60601-1:1995

Accessories equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC6950 for data processing equipment and IEC 60601-1-1 for medical equipment.) Furthermore all configurations shall comply with the system standard IEC 60601-1-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible to ensure the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult the technical services department or your local representative.

WARNING: This equipment should be connected using the power cord supplied by Clarity.

WARNING: To avoid risk of electric shock, this equipment must be connected to a supply mains with protective earth.

Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The RetCam Shuttle uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The RetCam Shuttle is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the RetCam Shuttle or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The RetCam Shuttle is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95%, 0.5 cycles 60%, 5 cycles 30%, 25 cycles >95%, 250 cycles	>95%, 0.5 cycles 60%, 5 cycles 30%, 25 cycles >95%, 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RetCam Shuttle requires continued operation during power mains interruptions, it is recommended that the RetCam Shuttle be powered from an uninterruptible power supply (UPS).
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	0.15-80 MHz, 3 Vrms, 80% 1 KHz AM	0.15-80 MHz, 3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the RetCam Shuttle, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Radiated RF IEC 61000-4-3	80-2500 MHz, 3/m, 80% 1 KHz AM	3 V/m	

WARNING: Interference may occur in the vicinity of equipment marked with this symbol. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

Input and Fuse

100-240V~

50/60 Hz, 250VA

T 3A / 250V

CAUTION: For continued protection against risk of fire, replace only with same type and rating fuse.

Safety Information

This medical equipment is in compliance with UL60601-1/CAN/CSA C22.2 No.601-M90

This medical equipment is IPX1 labeled and in accordance with IEC 60529.

European Authorized Representative address

EC REP

MediMark® Europe Sarl. 11, rue Emile Zola. BP 2332F-38033 Grenoble Cedex 2. FranceTel: +33 (0)4 76 86 43 22 Fax: +33 (0) 4 76 17 19 82e-mail: info@medimark-europe.com

FDA (USA) Notices

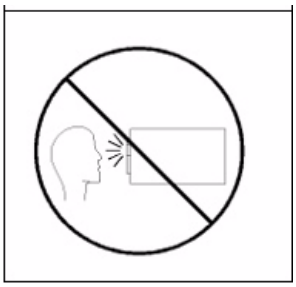
This device is listed with the United States of America (USA) Food and Drug Administration (FDA) for commercial distribution.

Device Trade Name	RetCam Shuttle
Product Code	86 HKI
Classification Name	Ophthalmic Camera
Classification Regulation Number	886.1120
Medical Device Classification	Risk Class II

Important User Safety Notices

1. Remove the lens and store it in the lens box and secure the handpiece in its storage compartment inside the cart before moving the cart to a new site.
2. Carefully inspect and clean the lens piece before each use. DO NOT use if the front lens of the lens piece is nicked or scratched.
3. Never contact the front of the lens piece with hard or sharp objects. This could damage the precision optics and sealing.
4. Unauthorized modifications or additions to the software or hardware of the system will void the warranty and could adversely affect the system function.
5. DO NOT AUTOCLAVE any part of this device. Refer to Chapter 8 Maintenance and Support for cleaning recommendations.
6. Do not use the white light source for longer than 5 cumulative minutes on the same eye during an exam.
7. Appropriately power down and unplug the unit and allow the light source bulb to cool before replacing it. Refer to the instructions to Replace Illumination Lamp on page 110.
8. Never connect the RetCam Shuttle to a network or any externally powered devices or peripherals *during imaging*.
9. Before using this equipment to acquire images from patient eyes, users must be trained in proper clinical technique by personnel authorized by Clarity.
10. The RetCam Shuttle is for use by or on the order of a health care professional.

Labels and Symbols



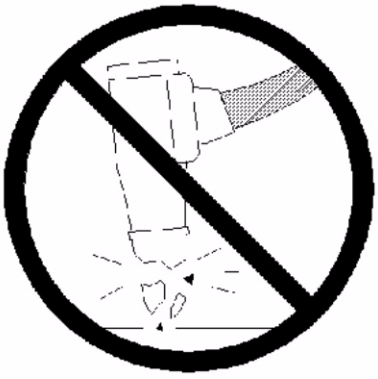
CAUTION:
DO NOT LOOK DIRECTLY INTO LIGHT SOURCE

BEFORE CONNECTING READ INSTRUCTIONS

Protective earth (ground)

Alternating current (AC)

Type BF Equipment (applied part is handpiece)

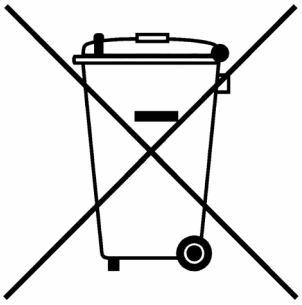


Do not use if dropped

Clean lens piece after use

IPX1

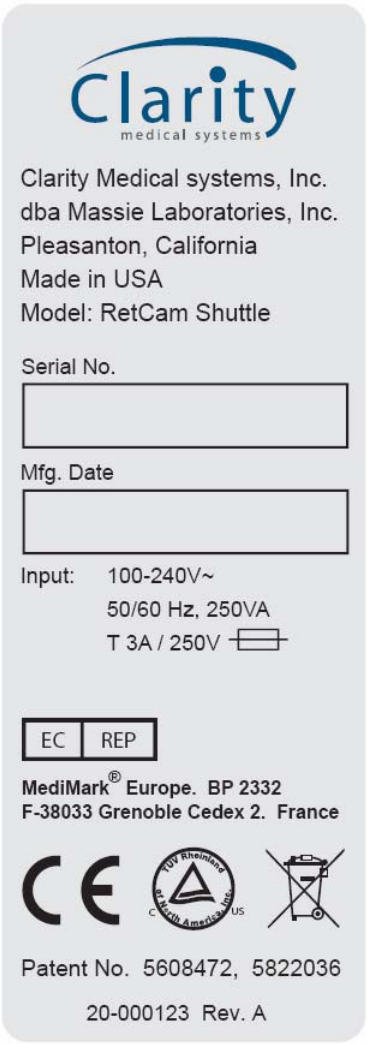
Footswitch in accordance with IEC 60529



Separate collection of waste at end-of-life as required by European directives.

Equipment suitable for direct current (DC) only using the indicated terminal. Notebook computer can be powered from this terminal.

Label


Clarity
medical systems
Clarity Medical systems, Inc.
dba Massie Laboratories, Inc.
Pleasanton, California
Made in USA
Model: RetCam Shuttle
Serial No.
Mfg. Date
Input: 100-240V~
50/60 Hz, 250VA
T 3A / 250V
EC REP
MediMark® Europe. BP 2332
F-38033 Grenoble Cedex 2. France
Patent No. 5608472, 5822036
20-000123 Rev. A

2 System Functions

This section addresses system level attributes and functions that are important to understand for general operating purposes, including:

- Power Cord and Power Connector, below
- Turning on the RetCam Shuttle, page 26
- Establish Site Awareness, page 28
- Status Bar, page 30
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- Lens Installation, page 36
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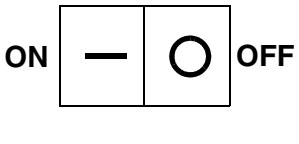
- Compatible Removable Media, page 37

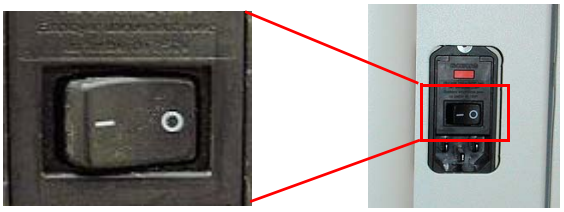
Figure 6 Main power switch

Power Cord and Power Connector

Power for the RetCam Shuttle enters the unit through the main power inlet, located on the lower right side of the rear panel of the Shuttle cart. The cart is wired for universal voltage input

The main power switch is located above the power cord inlet. It must be in the ON position to operate the Shuttle.





Note: Do not switch off or disconnect main power during live imaging. If you do, the live image stream will stop, and the system will not restart image acquisition when main power is restored. Therefore, before removing main power, it is best to end a live imaging session first. Start a new live imaging session only after reconnecting the AC power.

Turning on the RetCam Shuttle

1. Plug the main power cord from the RetCam Shuttle system into a properly grounded hospital grade electrical outlet and turn on the main power switch.

2. For imaging, if it is not already on, switch on the electro-optical box inside the lower door. This supplies power to the camera and other system components. (The notebook computer power outlet is always live when the main power is on and the power cord is plugged in.)

Figure 7 Lower door open showing electro-optical box

3. If not already connected, connect the notebook computer to the power supply and the USB video input cable.

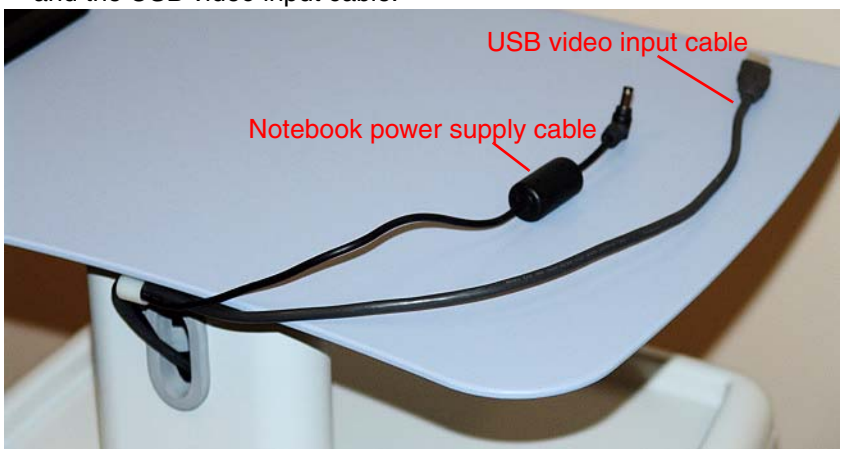


Figure 8 Computer power and USB (video) cables

4. Power on the notebook. If the Shuttle software does not start automatically, double click its desktop icon to start the system software. When the RetCam Shuttle software completes its start sequence, you will be prompted to establish site awareness for the system.

Establish Site Awareness

After you turn on the notebook computer and it completes its start sequence, the Site Awareness dialog appears, prompting you to identify the current physical location. No sites will appear in the list initially. You must create one before you can access the RetCam Shuttle functions.

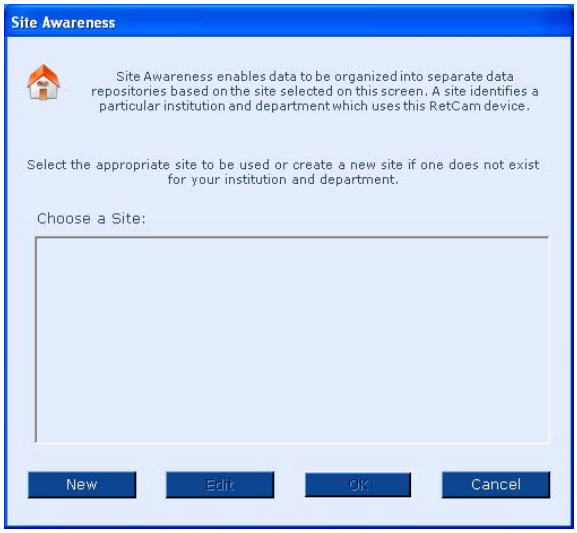

Site Awareness
Site Awareness enables data to be organized into separate data repositories based on the site selected on this screen. A site identifies a particular institution and department which uses this RetCam device.
Select the appropriate site to be used or create a new site if one does not exist for your institution and department.
Choose a Site:
New
Edit
OK
Cancel

Figure 9 Site Awareness dialog on first use

☞ **Note: All patient and image data is associated exclusively and irrevocably with the site under which it is acquired.**

Specify a New Site

To specify a new site, follow these steps:

1. In the Site Awareness dialog (Figure 9 above), click **New**. The Specify Site Information dialog appears.

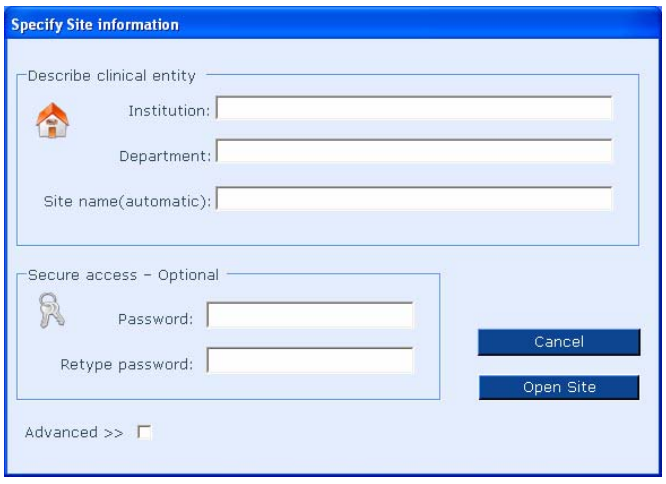


Figure 10 Specify Site Information dialog

2. Enter a name for the **Institution** and the **Department** and then press the **Tab** key. When you press the **Tab** key, the **Site name** will be completed automatically by combining the two names above it. You can override the automatic site name by typing in a name you choose.
3. In the Secure Access Options area, we strongly recommend you enter and then re-type a password in the indicated fields. If you do not, your system and its data will not be password protected.

☞ **Note: It is strongly recommend that you record the password you create in a safe, separate location to maintain access to the data associated with your site.**

WARNING: **If you lose the password, you will not be able to access any data associated with the site under which it was acquired. If you do lose the password, contact Clarity or your authorized distributor to assist you with its recovery. (See Technical Support Contact Information on page 114.)**

4. When finished, click **Open Site**. The RetCam Shuttle splash screen (see page 38 below) will appear, giving you access to the system software.

You can access the Site Awareness dialog and create a new site only by starting the system software. If you wish to create multiple sites, you can exit and restart the system software and follow the same procedure.

Select a Site

After the first time you specify a site, the Site Awareness dialog will appear showing all created sites.

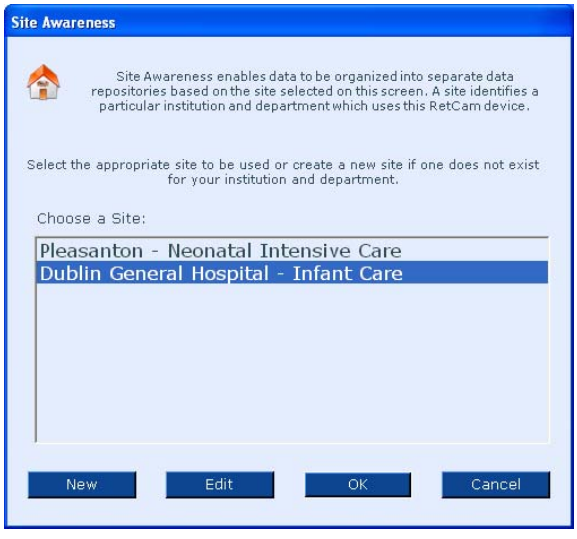

Site Awareness
Site Awareness enables data to be organized into separate data repositories based on the site selected on this screen. A site identifies a particular institution and department which uses this RetCam device.
Select the appropriate site to be used or create a new site if one does not exist for your institution and department.
Choose a Site:
Pleasanton - Neonatal Intensive Care
Dublin General Hospital - Infant Care
New
Edit
OK
Cancel

Figure 11 Site Awareness dialog after first use

To access the system, you must select a site from the list in the Site Awareness dialog, or you may create a new site if you wish. (For details, see Specify a New Site on page 28.)

☞ **Note: All patient and image data is associated exclusively and irrevocably with the site under which it is acquired.**

When you select a site, click **OK** to continue to the RetCam Shuttle splash screen (see page 38 below).

Edit a Site

To edit site information for the currently selected location:

1. Click **Edit** in the Site Awareness dialog. The Edit Site Information dialog appears, which is visually and functionally the same as the Specify Site Information dialog (see Figure 10 on page 28).
2. Edit the fields as desired and click **Save**. You will return to the Site Awareness dialog, from where you can select a site and continue.

Status Bar

The status bar appears at the bottom of all RetCam Shuttle screens.

Figure 12 RetCam Shuttle status bar

It displays the date, time and system status information. The following status indicators can appear.

- I = Indexing. The system is reading the data on a media or in the hard drive buffer, and checking the data against the system's database.
- "A" = Caps Lock (for the keyboard)
- "1" = Num Lock (for the keyboard)

Turning Off the RetCam Shuttle

To turn off the system, use the **Shutdown** button in the upper right corner of most screens. When you click **Shutdown**, the system gives you three options, as illustrated below:

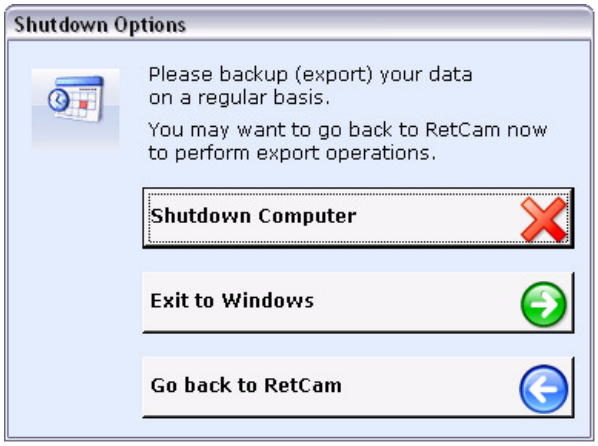

Shutdown Options
Please backup (export) your data on a regular basis.
You may want to go back to RetCam now to perform export operations.
Shutdown Computer
Exit to Windows
Go back to RetCam

Figure 13 Shutdown Options dialog

This dialog reminds you to backup (export) your data on a regular basis. To backup before shutting down, click **Go back to RetCam** and use the export function (see Export on page 75 for details).

To proceed with shutdown, click **Shutdown Computer**, which safely closes the RetCam Shuttle application and powers down the correct components in the normal sequence.

To exit the RetCam Shuttle application without shutting down the computer, click **Exit to Windows**.

If the Computer Hangs

If the computer hangs (stops responding), you may have to shut it down directly, but in doing so, **you may lose any unsaved data. Therefore, please wait a sufficient time to make sure it is not simply busy!** To shutdown the computer directly, as with any Windows XP system, hold down the computer on/off switch for about three to five seconds.

Emergency Shutdown

WARNING: Do not use the emergency method below unless necessary because data corruption can occur.

In an emergency, turn off the main power switch at the power inlet on the rear of the cart or pull the plug from the wall outlet. These actions will remove power from the entire system, although the notebook computer may continue to operate using its internal battery.

Turning Off for Extended Periods

If you are not going to use the system for an extended period (e.g., a day or more), it is advisable to turn off the electro-optical box to preserve the life of the illumination lamp. The electro-optical box is found inside the lower door at the left. Its power switch is on the right side.

☞ **Note: Turning off the power switch on the electro-optical box removes power to all system components except for the notebook computer. The notebook power outlet on the electro-optical box is live whenever the main power is on.**

Alternatively, you may turn off the main power switch at the power inlet on the rear of the cart. This removes power from the entire system, including the notebook (which may still run by its internal battery).

The Electro-Optical Box

The electro-optical box (EO box) is akin to the central nervous system of the RetCam, receiving your input from the footswitch and camera, and directing its output to camera, computer and notebook display. It contains the illumination lamp and light intensity controllers, focus, camera and footswitch controllers, and passes live images from the camera to the screen. This section introduces its components and functions you can control with it.

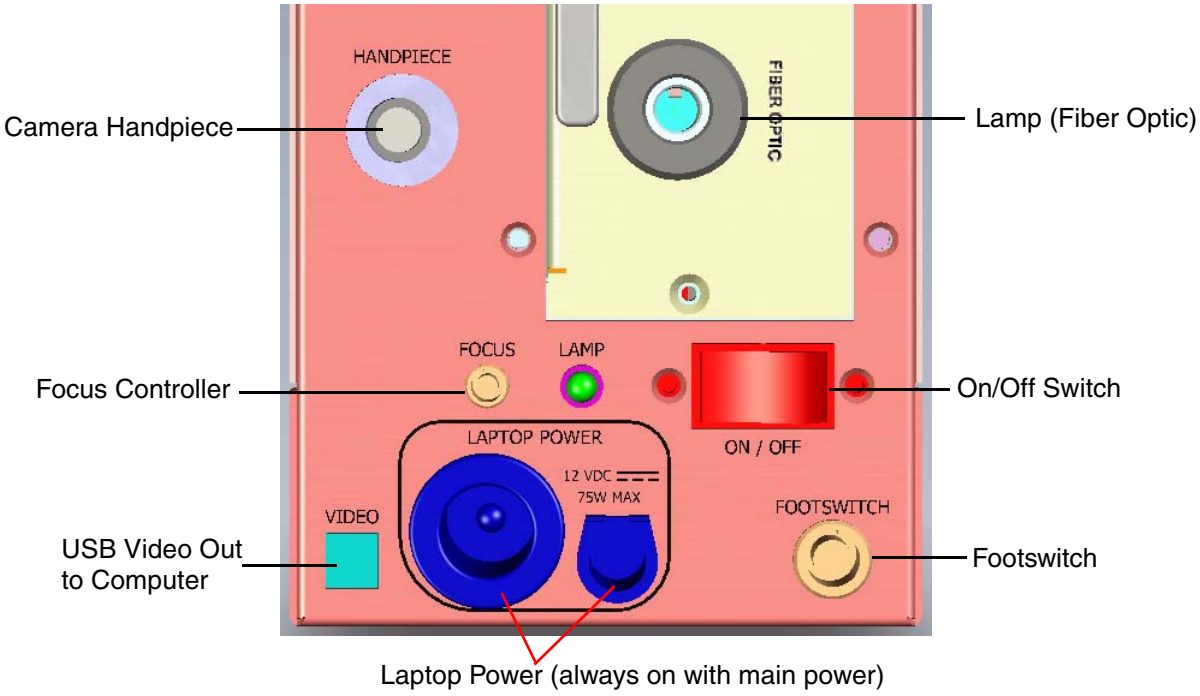


Figure 14 Electro-optical box drawing (lower portion) showing connectors

☞ **Note: It is not necessary to remove any of the connectors for use, storage or transportation.**

WARNING: Do not remove or insert the camera connector while the RetCam Shuttle system is powered on. Before connecting or disconnecting the camera connector, shut down the system through the software and then switch off the power at the main power switch. IT IS NOT SUFFICIENT TO SHUT DOWN THE COMPUTER ONLY. YOU MUST SWITCH OFF POWER AT THE MAIN POWER SWITCH. (You can insert or remove the fiber optic connector at any time.)

The **Lamp (Fiber Optic)** connector is a receptacle for insertion of the handpiece fiber optic line, which is part of the camera interconnect cable.

WARNING: Do not look directly into the Lamp (Fiber Optic) opening when the EO box is on.

The **Focus** connector is a direct insert receptacle for insertion of the (white) focus motor cable, which is part of the camera interconnect cable.*

- Insert/Detach: Align the red dot on the connector with the red dot on the Focus port and insert. To detach, pull back on the connector, but not the wire. The focus connector is not threaded!

The **Camera Handpiece** connector is a receptacle for insertion of the black camera controller cable, which is part of the camera interconnect cable.*

- Insert/Detach: To insert, align the slot in the port with the pin on the connector, insert and screw in clockwise to secure. To detach, unscrew (counterclockwise) the connector sleeve and pull out.

Camera Color Balance Adjustment

The electro-optical box provides buttons near the top left by which you can adjust the black and white camera color balance.

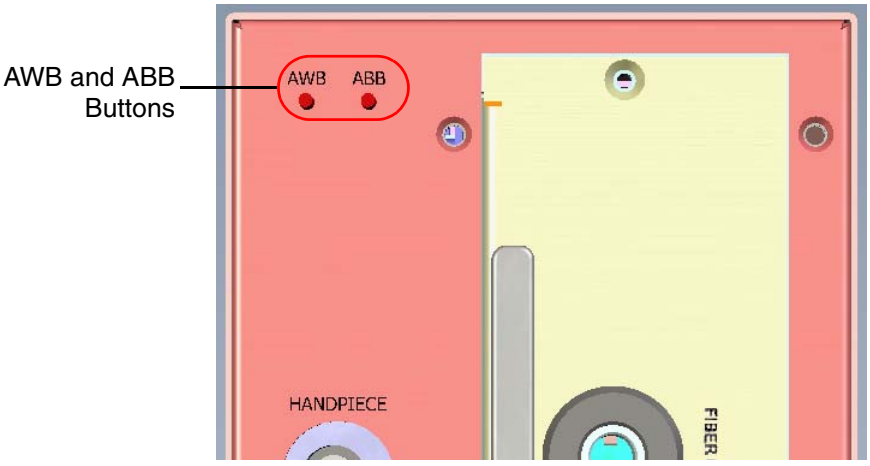


Figure 15 Electro-optical box drawing (upper portion) showing color balance buttons

- The **ABB** button is for automatic black balance of the camera. Refer to Automatic Black Balance (ABB) on page 34 for instructions.

- The **AWB** button is for automatic white balance of the camera. Refer to Automatic White Balance (AWB) on page 34 for instructions.

☞ **When to Adjust Color Balance: Clarity Medical performs these procedures at the factory before shipment. You should have to adjust the camera color balance only rarely, and then only in the following circumstances:**

- **The colors of the live image are very different from the real object.**
- **If you suspect that the AWB or ABB button was pressed accidentally.**

When one of these circumstances apply, we recommend you perform first a black balance and then a white balance, in that order.

If you find that you must adjust the color balance frequently (without having accidentally pressed one of the buttons), please contact Clarity Customer Service. See page 114 for Technical Support Contact Information.

Automatic Black Balance (ABB)

The automatic black balance adjustment corrects the camera controller to display black accurately. To adjust the automatic black balance, follow these steps:

1. With the RetCam Shuttle running, initiate a new imaging session and check on screen to see that the camera is working (receiving an image).

☞ **Note: To start a new imaging session, you must select or create a patient record.**

2. Disconnect the lamp (fiber optic) cable from the EO box. The handpiece should now not be projecting any light.
3. Hold the front of the handpiece, with or without a front lens, against a towel or soft cloth to block all light from entering the camera.
4. Press the **ABB** button on the front panel of the EO box for about 1 second and release. The characters **"ABB"** will appear superimposed and blinking on the live (black) image.

   The characters **"ABB"** will stop blinking and the characters **"ABB OK"** will appear for approximately 1 second. Black balance adjustment is successful.

If the characters **"ABB NG"** appear, it means that the automatic black balance cannot be performed (NG = no good). Usually this is due to light leaking into the black image. Try blocking ambient light more completely and press **ABB** again. If the problem persists, please call the manufacturer or your authorized representative.

Automatic White Balance (AWB)

The automatic white balance adjustment corrects the camera controller to display colors accurately.

☞ **Note: This procedure should be done under minimal room lighting to simulate how a retina being imaged is screened from room lighting (by the handpiece).**

To adjust the automatic white balance, follow these steps:

1. Perform automatic black balance as described above.
2. Connect the lamp (fiber optic) cable back in its EO box receptacle. The handpiece should now be projecting light. Adjust the handpiece light level to that of normal usage.
3. Attach any front lens, if not already present. See Lens Installation on page 36.
4. Place a blank, white piece of paper on a nearby table. Hold the handpiece perpendicular to the paper. Hold the tip of the lens approximately 2” (50 mm) from the paper, so that the center of the image on the screen appears uniformly bright. The outer area or ring of the image may be slightly gray or yellow in color.
5. Press the **AWB** button on the front panel of the EO box for about 1 second. The characters **“AWB”** will appear superimposed and blinking on the live (white) image.

   The characters **“AWB”** will stop blinking and the characters **“AWB OK”** will appear for approximately 1 second. White balance adjustment is successful.

If the characters **“AWB NG, LEVEL NG”** appear, automatic white balance adjustment cannot be performed because the light level is too high or too low. Adjust the light level up or down as indicated and repeat steps 4. and 5. again. If **“AWB OK”** still does not appear, try adjusting the ambient (room) lighting up or down, or vary the distance from the front lens tip to the paper. If the problem persists, please call the manufacturer or your authorized representative.

Lens Installation

The diagram below illustrates how to install all lens pieces. The instructions are also repeated below.

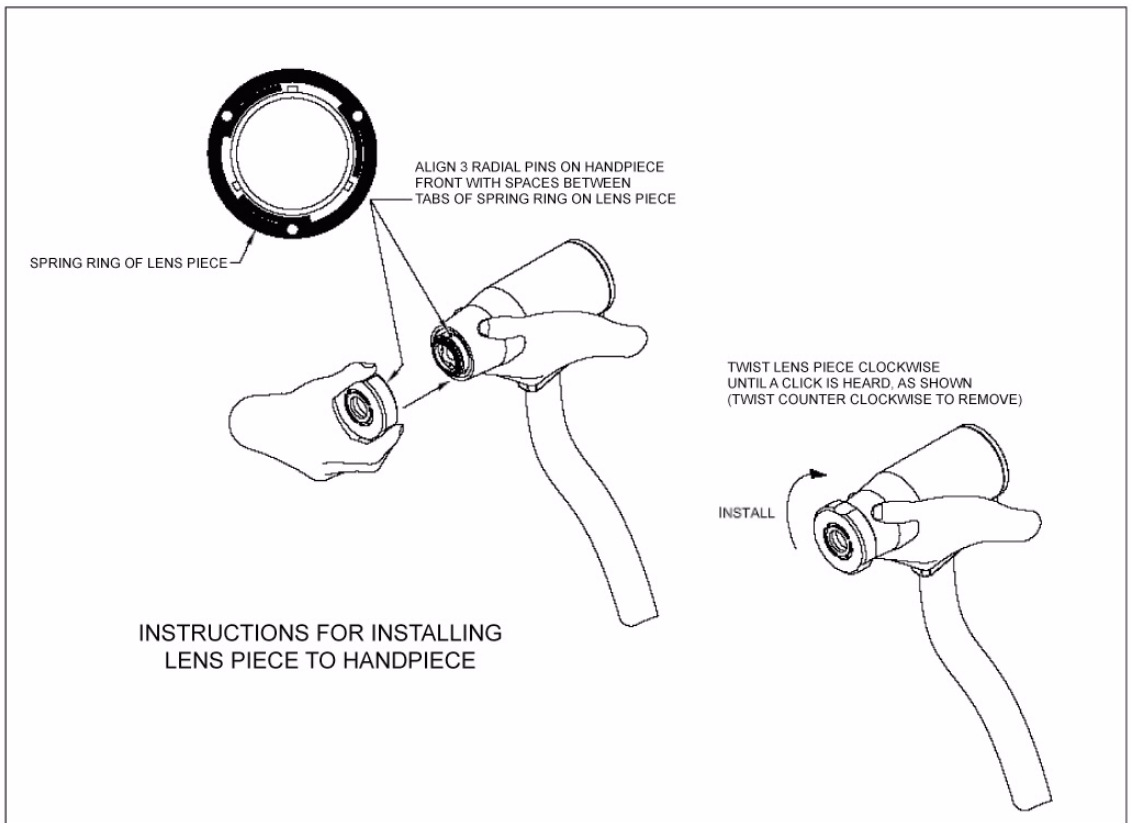

ALIGN 3 RADIAL PINS ON HANDPIECE
FRONT WITH SPACES BETWEEN
TABS OF SPRING RING ON LENS PIECE
SPRING RING OF LENS PIECE
TWIST LENS PIECE CLOCKWISE
UNTIL A CLICK IS HEARD, AS SHOWN
(TWIST COUNTER CLOCKWISE TO REMOVE)
INSTALL
INSTRUCTIONS FOR INSTALLING
LENS PIECE TO HANDPIECE

Figure 16 Instructions for installing a lens piece to the handpiece

Instructions for Installation of All Lens Pieces

1. Fit the lens piece on the handpiece, aligning the 3 radial pins on the front of the handpiece with the spaces between the tabs of the spring ring on the lens piece.
2. Twist the lens piece clockwise (as shown) until you hear a click, indicating that the lens piece is locked in place.

WARNING: Always inspect the lens before use for damage such as chips, cracks or roughness that could injure the patient's eye.

Storage and Backup

The hard drive on the RetCam Shuttle notebook computer serves as the initial storage media. Images taken directly from RetCam Shuttle are stored on a partition of the hard drive for easy access. This area on the hard drive is called the FIFO buffer, which stands for "First In First Out." Its capacity is about 10 GB less than the full hard drive capacity. If the partition becomes full, the oldest files are deleted to

make room for the new files. **This is done without warning!** Each RetCam still image takes about 600 KB of disk space. Depending on usage, the FIFO buffer can contain several years of data.

WARNING: Permanent data loss is possible if no backup solution is employed.

To preserve data before it starts to be removed from the FIFO buffer, we recommend you use a backup solution; there is no automatic backup. You can implement backup using the RetCam Shuttle Data Transfer functionality via your office network or USB connection to an removable USB mass storage device—see page 72 for details.

Backup Recommendation: Network or Removable USB Mass Storage Device

For long-term backup, we recommend backing up to another computer on your office network, preferably a server-class computer with large capacity and redundant storage functionality (Redundant Array of Independent Disks, or RAID). Since USB devices can be directly addressed like a network location, and USB devices can have very large capacity, we also recommend the use of a removable USB mass storage device. For secondary backup in this scenario, you may consider using a second removable USB mass storage device.

Compatible Removable Media

For transfer or backup of smaller amounts of data, you can use a USB memory stick. Like any Windows XP computer, the Shuttle computer supports nearly all USB devices. While the RetCam Shuttle can read from all standard kinds of CDs, DVDs and USB devices, it can write only to USB devices during data transfer. It cannot write to CD-R, CD-RW, DVD±R nor DVD±RW.

☞ **Note: From the RetCam Shuttle software, you can write (transfer) data to network folders or USB devices; you cannot write to CD-R, CD-RW, DVD±R nor DVD±RW.**

☞ **Note: Clarity Medical Systems has successfully tested many "SanDisk" brand USB memory sticks. Some USB sticks require special formatting before use with RetCam systems and we recommend purchasing pre-formatted USB sticks directly from Clarity. Call (800) 215-6005 toll-free in the US and ask for part number 03-12-025. If you are experiencing problems with your USB stick contact Clarity Customer Support. (See complete Technical Support Contact Information on page 114.)**

3 Start, Patient Select, New Session

This chapter covers the functional prerequisites for image acquisition or review, which include accessing the system software, finding or adding a patient, and reviewing the patient's history. Then it covers image acquisition itself. These functions are provided through the following screens:

- Start: Splash Screen, below
- Patient Select Screen, page 39
- History Screen, page 45
- New Session Screen, page 49

Start: Splash Screen

After you have established site awareness, the Splash screen appears, signaling that the system is ready for use.

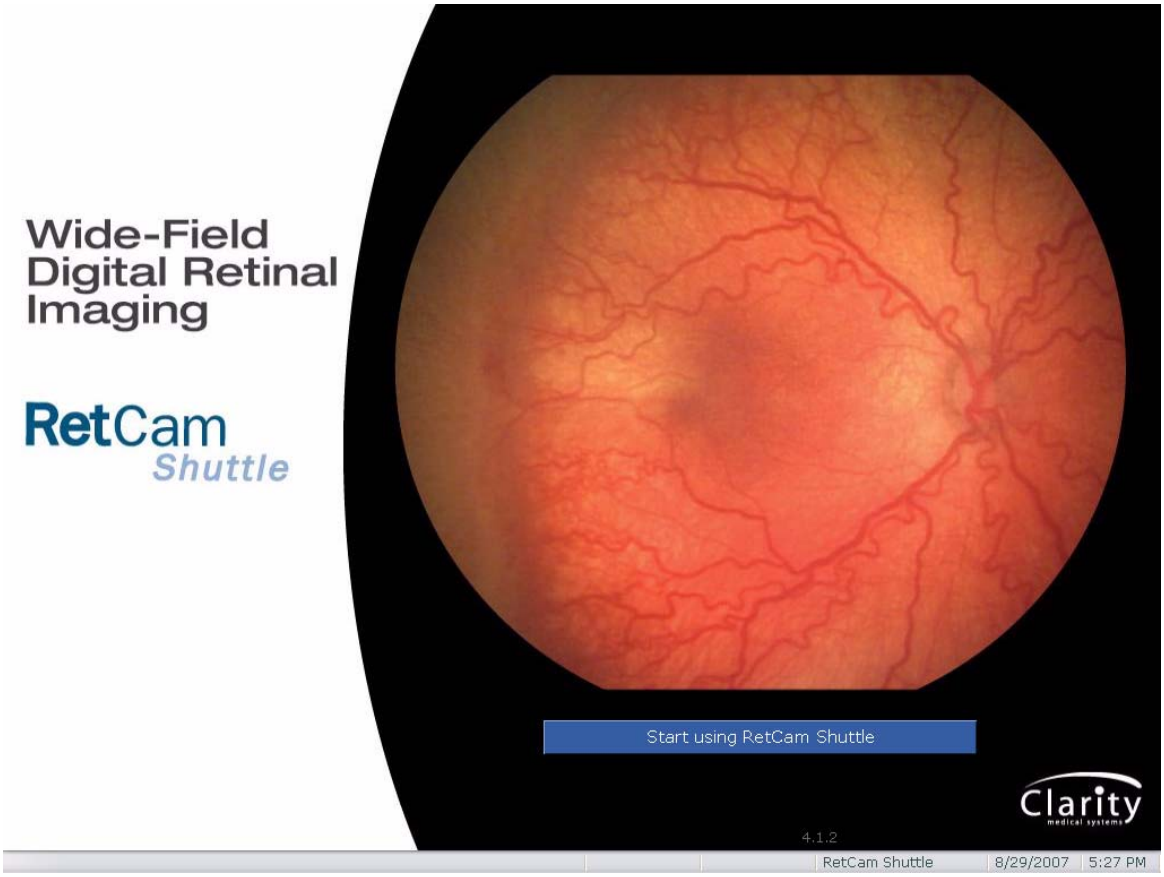


Figure 17 RetCam Shuttle splash screen

To begin using the system, click **Start using RetCam Shuttle**. When you do, the Patient Select screen appears, providing you access to the patient list. To either acquire or view images, you must select (or add) a patient.

Patient Select Screen

The Patient Select screen appears first after the Splash screen. You can access it any time by clicking its tab or pressing F1 on the keyboard.

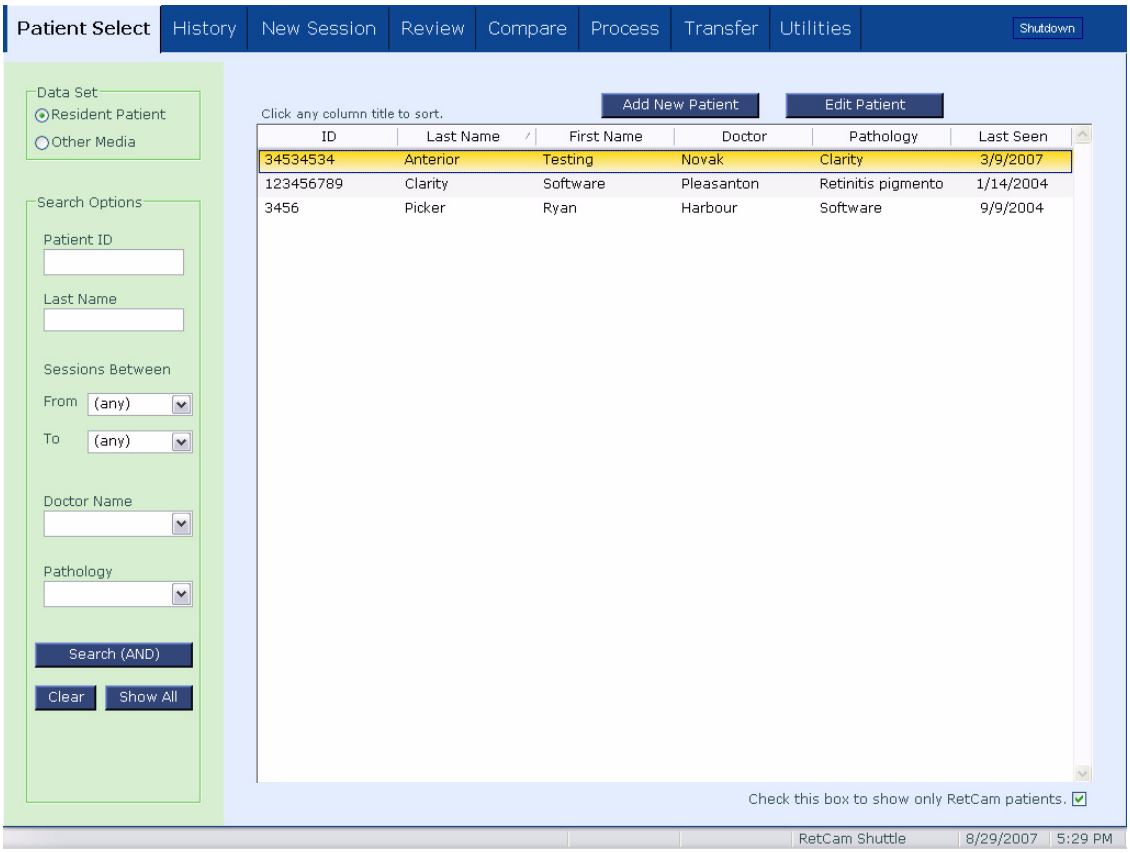


Figure 18 Patient Select screen

The Patient Select screen opens showing the complete list of resident patients. Click anywhere on the row of the desired patient and then select the History tab to show that patient's history (see History Screen on page 45).

Patient List Columns

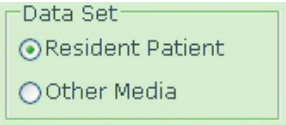
The patient list has the following columns:

Patient ID	Patient Last Name	Patient First Name
Doctor	Pathology	Last Session Date

Sort List by Columns

Click on any column title to sort the data by that parameter. Each click on a title toggles the sort between ascending and descending order, alphabetically and/or numerically. (Numbers precede letters in ordering.)

Select Data Source



The Data Set area at upper left enables you to specify whether to display resident patients (from the local database) or patients found on removable media installed on the notebook computer. The default is resident patients.

You can apply all RetCam Shuttle functions to the patient records and images found on the source you select, but you cannot add or edit a patient record while **Other Media** is selected.

Resident Patients

Selected by default, **Resident Patient** includes every patient whose records were created or added to the database while attached to this RetCam Shuttle notebook while the current site was selected—see Establish Site Awareness on page 28 for details.

☞ **Note: All patient and image data is associated with the site under which it is acquired. You cannot access data created while any other site was selected, except by adding non-resident records to the local database or using Data Transfer (see page 72).**

When you select **Resident Patients**, the **Add New Patient** and **Edit Patient** buttons are available. That is, you can create and edit resident patient records. Also, you can add the records of non-resident patients from installed media, thus making them resident patients, whose records you could then edit. For details, see Add to Resident Buttons on page 41.

Other Media

Click **Other Media** to access RetCam images on removable media (e.g., USB device) installed on the RetCam Shuttle notebook. You can install removable media in either the CD/DVD drive or a USB port. The RetCam Shuttle can read from all standard kinds of CDs, DVDs, and USB devices. The patient list displays all RetCam data and images found on the installed disks or devices, provided that automatic indexing is enabled. No patient data will appear if automatic indexing is off.

☞ **Note: Automatic indexing is off by default. To turn on automatic indexing, go to the Utilities screen and select the Auto Index External Media Checkbox — see page 97.**

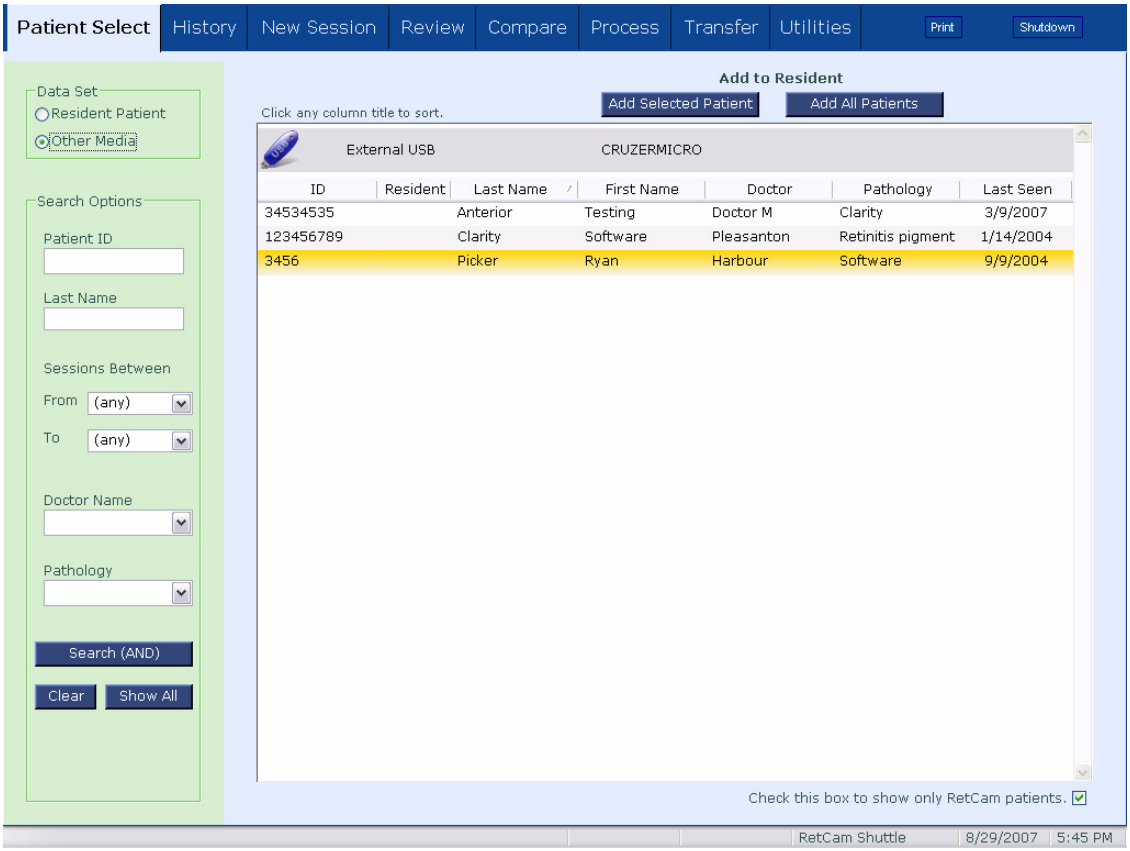


Figure 19 Patient Select screen accessing removable media

These images may or may not be from patients resident on this RetCam Shuttle system. Resident patients will be noted with a ✓ mark. When you select **Other Media**, the **Add New Patient** and **Edit Patient** buttons are not available. That is, you cannot add a new patient record nor edit a patient record while **Other Media** is selected.

Add to Resident Buttons

When you select **Other Media** and the system finds RetCam records on any installed media, the buttons **Add Selected Patient** and **Add All Patients** appear above the patient list. The patient list displays all patients found on the installed media by default, though you can Search for Patients as explained on page 42.

- **Add Selected Patient**

  Select the desired patient in the list and then click **Add Selected Patient** to add this patient to the resident database.

- **Add All Patients**

  Click **Add All Patients** to add all patients from an installed removable media to the resident database.

☞ **Note: When you begin a new imaging session for a non-resident patient, the system automatically adds this patient to the current RetCam Shuttle site as a resident patient.**

A floppy disk icon on a thumbnail in the Review, Compare, Process, and Transfer screens indicates that the image can be found on media that is not currently installed in the system.

Adding RetCam 120 Data to the FIFO Buffer

The RetCam Shuttle software provides a way to add RetCam 120 data to the hard drive FIFO buffer area that eliminates the need to insert old RetCam 120 disks. If you have RetCam 120 data you wish to add to your RetCam Shuttle, contact technical support for assistance.

Search for Patients

The Search Options area on the left side enables you to search for patients using one or more of the available search fields: **Patient ID**, **Patient Name**, **Sessions Between** [date range], **Doctor Name,** and **Pathology**. Enter search criteria in a field and click **Search** to populate the patient list with all patients who match the entered text for all criteria you used.

- Click the **Show All** button to display all resident patients at any time.
- Click **Clear** to clear all search fields so you can start a new search.

Search by Patient ID

Type in the whole patient ID or just the first few characters (usually numbers) and click **Search**. The list will display all entries that start with the characters entered.

Search by Last Name

Type in the whole last name or any portion of it. The list will display all patients whose last name contains the text you entered.

Search by Date range

To specify a date range, under Sessions Between, click on the down arrow next to the **From** field and the **To** field and select a date for each. The list will display all patients with imaging sessions created within the date range specified.

Search by Doctor

Select from the drop-list, or type in a name. Only doctors of resident patients are included in the drop-list.

Search by Pathology

Select a pathology from the drop-list, or type in an entry. Only pathologies of resident patients are included in the drop-list.

Add a New Patient Record

When **Resident Patient** is selected in the Data Set area at upper left, the **Add New Patient** button is available. Click it to add a new patient record. The Patient Information dialog appears, with all fields empty.

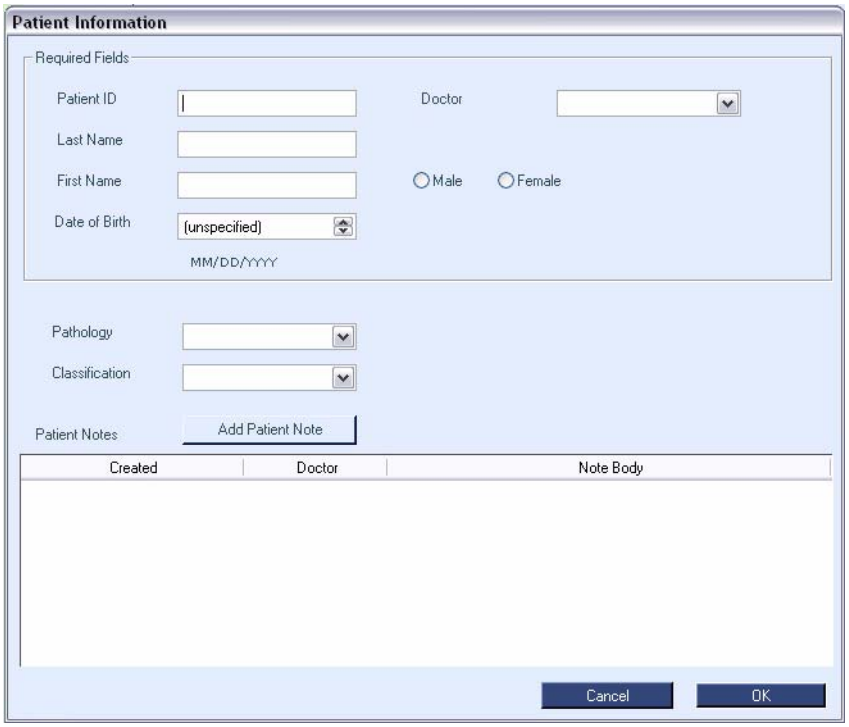


Figure 20 Patient Information dialog

Required Fields

To create a new patient record, enter information at least in the required fields, which are:

- Patient ID: Type letters and/or numbers, usually a unique number to identify the patient.
- Patient Last Name: First letter is capitalized automatically when stored.
- Patient First Name: First letter is capitalized automatically when stored.
- Patient DOB: Enter patient's date of birth. Age is displayed automatically.
  - For patients under 2 years, age is displayed in months and weeks.
  - For patients over 2 years, age is displayed in years and months.
- Doctor's Name: Select from the drop-list or type in a new name. First letter will automatically be capitalized when stored. Once a name is entered it becomes part of the drop-list. Only doctors of resident patients are included in this list.
- Gender: Click radio button to select.

☞ **Note: The system does not prevent you duplicating patient information. In other words, you can create multiple patient records with the same name and patient ID if you wish.**

Optional Fields

You can also add data in the following optional fields.

- Pathology: Select a pathology from the drop-list or type in a new pathology. All pathologies previously saved to a patient record appear in the drop-list. Only pathologies of resident patients are included.
- Classification: Enter in this field a specific category for the pathology in the field above. Select a classification from the drop-list or type in a new classification, which will become a part of the drop-list.
- Patient Notes: To add notes for the patient, click **Add Patient Note**. A new note entry will open with a date stamp and doctor identified. You can begin typing notes at the cursor in the Note Body column. You cannot change notes after typing them in.
  - To add more notes later, edit the patient record (as explained in Edit a Patient Record on page 44) and click **Add Patient Notes**.

  Additional Optional Fields for ROP Patients

  The following data fields appear when the patient is under one year of age according to the birth date entered.

  - Birth Count: Select single, twins, triplets, etc.
  - Gestational Age: Enter gestational age in weeks.
  - Birth Weight: Enter patient's birth weight in grams.

When finished entering information, click **OK**. The patient record is created and highlighted automatically on the Patient Select screen.

Edit a Patient Record

When **Resident Patients** is selected in the Data Set area at upper left, the **Edit Patient** button is available. With the desired patient selected, click **Edit Patient** to edit that patient record. The Patient Information dialog appears showing the current data in the fields. Edit the fields as desired and/or use the drop-lists to select options for **Doctor Name**, **Pathology**, and **Classification**.

When finished editing, click **OK** to save your changes. A confirmation dialog appears, prompting you to confirm or cancel your changes.

Print Patient Report

Click **Print** to print the data currently displayed in the patient list on the report printer.

Complete Report prints all the displayed fields plus expanded sessions, with individual session numbers and dates.

History Screen

The History screen appears when you select its tab or press F2 on the keyboard. Select the desired patient first to display that patient's history.

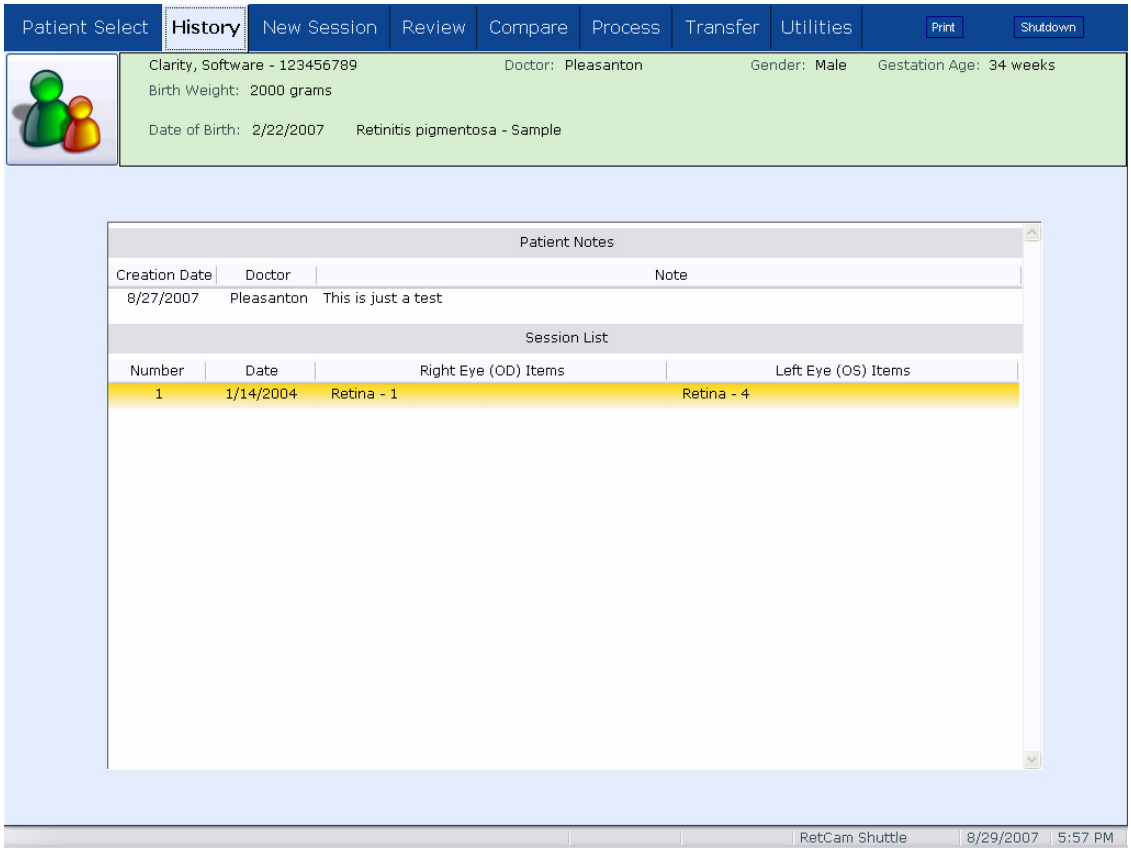


Figure 21 History screen

For the currently selected patient, the History screen displays patient notes and a session list that includes a list of images (items) for each session by eye.

Columns in the session list provide the following data:

- Session Number
- Session Date
- Image type and quantity in that session, under Right Eye (OD) Items and Left Eye (OS) Items

Patient/Session Selector

Click on this icon to:

- select another session for this patient, or
- select another patient

The Patient List tab appears, sorted by last name.

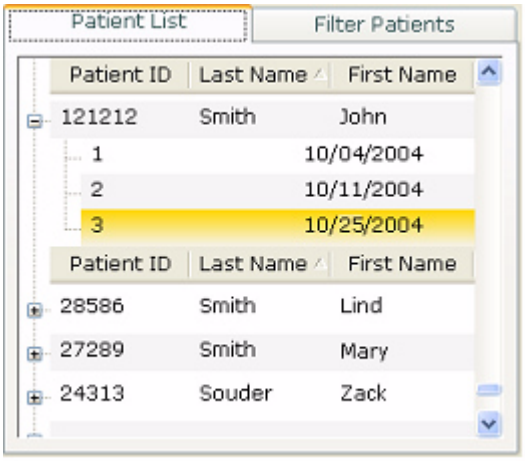


Figure 22 Patient List tab

The Patient List displays all patients from the last source you selected (resident patients or other media). If you have a very large database, the list may take a while to appear.

Scroll the list to find and select the desired patient. Use the expandable tree structure to select another patient or a different session. Click on the boxed plus sign ⊞ next to the Patient ID to display the list of sessions for this patient. Click on a session to highlight the session and access its images.

When a patient's session list is expanded, click on the boxed minus sign ⊟ to contract it.

For further search options, click on the Filter Patients tab. These search options are the same as the options on the Patient Select screen. Refer to Patient Select Screen on page 39 for a description.

Print Patient History or ROP Report

Click **Print** to print the currently displayed patient history on the report printer. For ROP patients, it offers the option to print the ROP report.

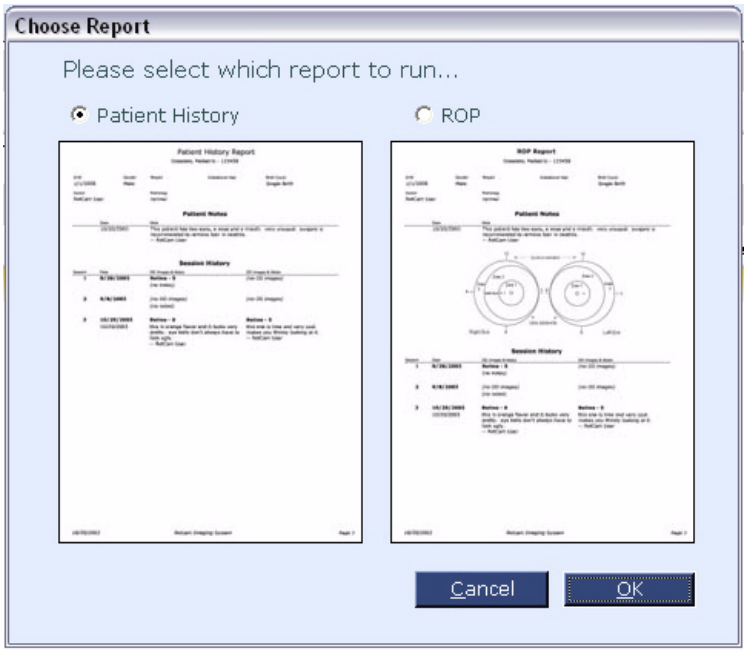


Figure 23 Choose Report dialog

ROP Report

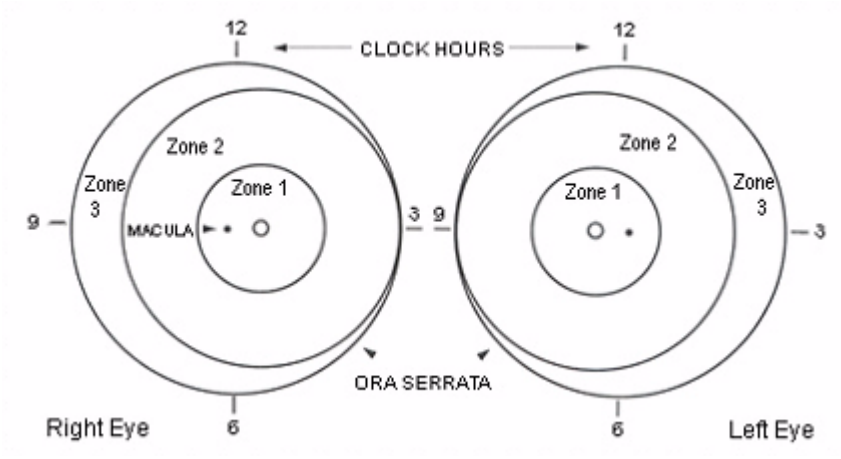
Jones, Indy - 23223

DOB	Gender	Birth Weight	Gestational Age	Birth Count
11/01/2003	Male	1500 gms	32 weeks	Twins

Doctor	Pathology
Spock	ROP

Patient Notes

Date	Notes
11/10/2003	6 weeks premature, can be released in 4 weeks -Spock



Session History

Session	Date	OD Images & Notes	OS Images & Notes
1	11/10/2003	Retina-12 Detached retina - Spock	Retina-8 Ridge at 3 o'clock, Zone 2 - Spock

Figure 24 Example of an ROP report printout

New Session Screen

The New Session screen appears when you select its tab or press F3 on the keyboard. Use the New Session screen to start a new imaging session, whether for still images or video recording.

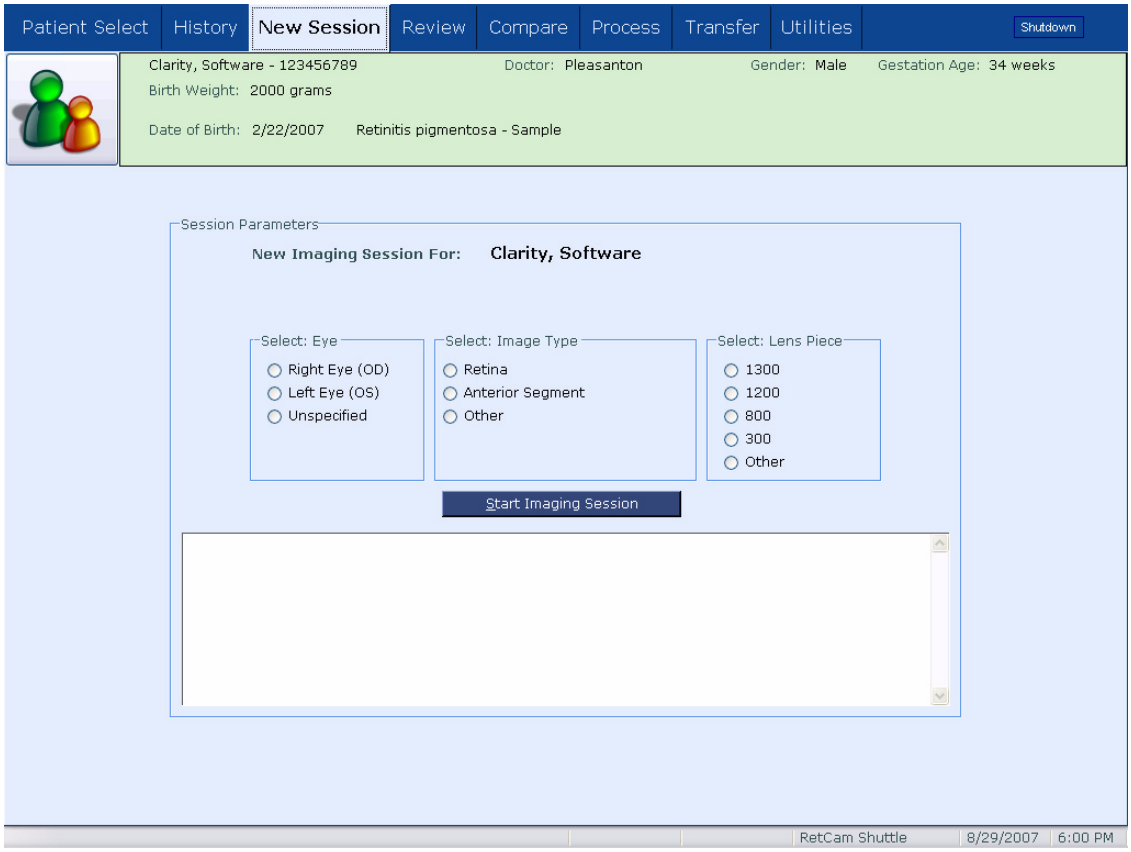


Figure 25 New Session screen

☞ **Note: Before imaging, make sure you have selected the correct name for the patient. If images are stored under the wrong patient's name, it is not possible to change later.**

Start Imaging

Before you can start imaging, you must select options for eye, image type and lens piece. For each of these, if none is selected, an error indicator will display if you try to start imaging.

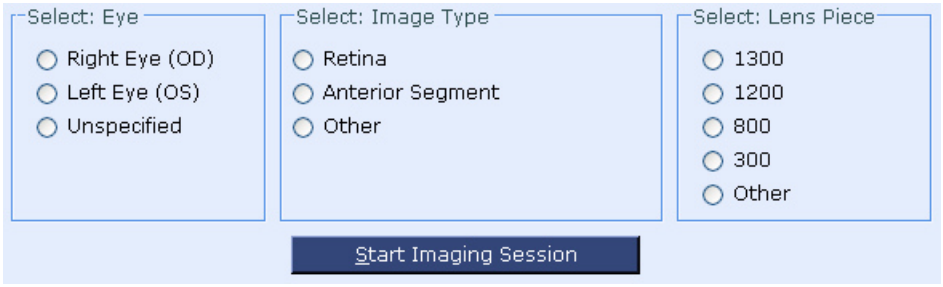


Figure 26 Select options for eye, image type and lens piece

Follow these steps to start imaging:

1. In the Select Eye area, select the radio button for **Right Eye (OD), Left Eye (OS)** or **Unspecified.**
2. In the Select Image Type area, choose **Retina, Anterior Segment** or **Other**
3. In the Select Lens Piece area, select the lens you are using: **1300** (ROP), **1200** (Children's), **800** (Posterior), **300** (High Mag), or **Other.**
4. When you have made all 3 selections, click **Start Imaging Session**. If the electro-optical box is on and operating correctly, a live image appears on screen.
5. In the Mode area at upper right, select **Still** or **Video** mode. These modes are explained in more detail next.

Still Mode

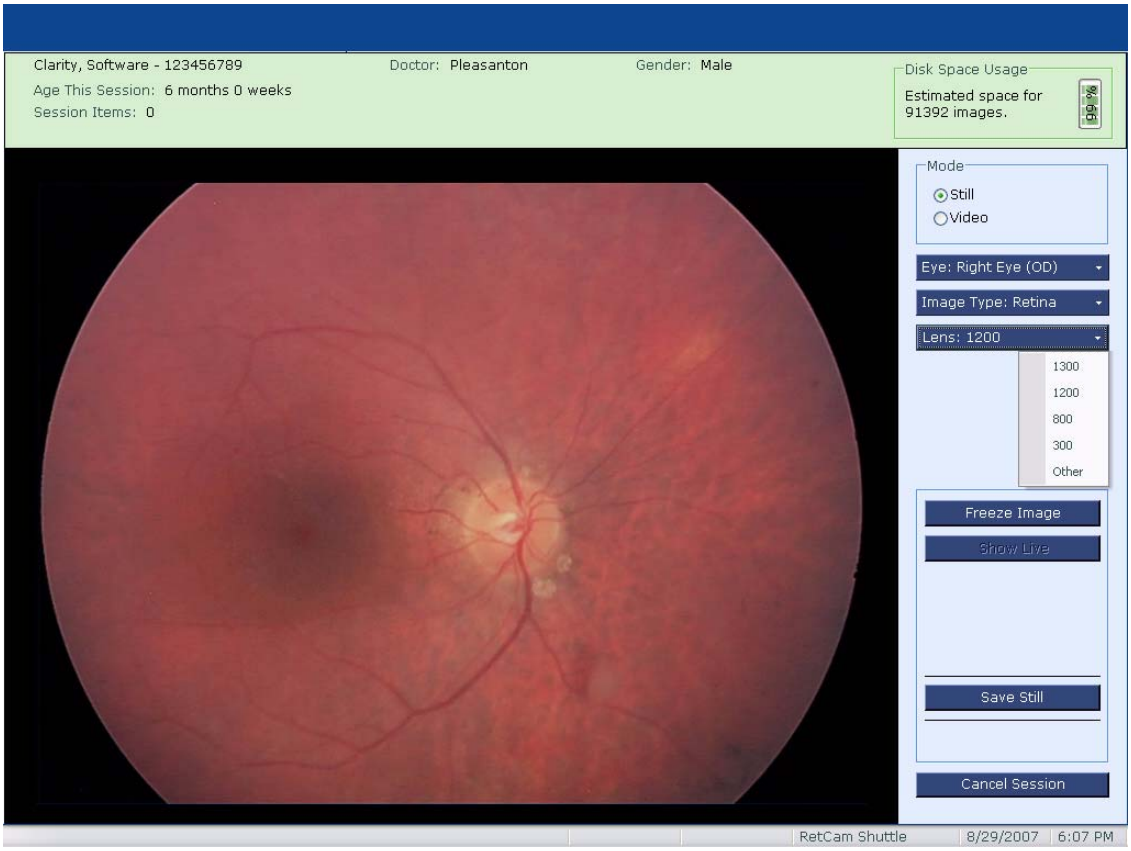


Figure 27 Live imaging screen (in still mode)

In still mode, the following buttons are available on screen:

- **Eye [OD or OS]:** Drop-list enables you to change to other eye
- **Image Type [Current type]:** Drop-list enables you to specify image type
- **Lens [Current lens type]:** Drop-list enables you to specify lens type in use
- **Freeze Image:** Freezes image on screen but does not save image
- **Show Live:** Unfreezes image and returns to live video
- **Save Still:** Saves the current image to the hard drive FIFO buffer
- **Cancel Session:** Ends the imaging session

Footswitch Capture

You can also save an image by pressing the central **Snap** button on the footswitch. In still mode, each press of the button saves one image.

Keyboard Capture

You can press **'S'** (for save) on the keyboard to save the current image. This is especially useful to save still images while viewing a recorded video.

Changing Right Eye (OD) / Left Eye (OS)

To image the other eye in the same session, click on the drop-list for **Eye** and select the other eye (OD or OS). Eye is saved with the image.

☞ **Note: Since you have this option, it is important to be careful that you select the correct eye before you save the image. Be particularly aware if both eyes are captured in one video clip, and then you save still images from it. You must select the correct eye before you save each still image from the video.**

Changing Image Type

Click on the **Image Type** drop-list to select **Retina, Anterior Segment,** or **Other** during this imaging session. All selections record the images in color. Image type is saved with the image.

Changing Lens

You can also select a different lens piece during imaging. Click on the **Lens** drop-list to select **1300** (ROP), **1200** (Children's), **800** (Posterior), **300** (High Mag), or **Other**. Lens piece selection is saved with the image.

Video Mode

☞ **Note: The video buffer can capture about 30 seconds of video. Depending on the current state of the system, the size of the video buffer may vary.**

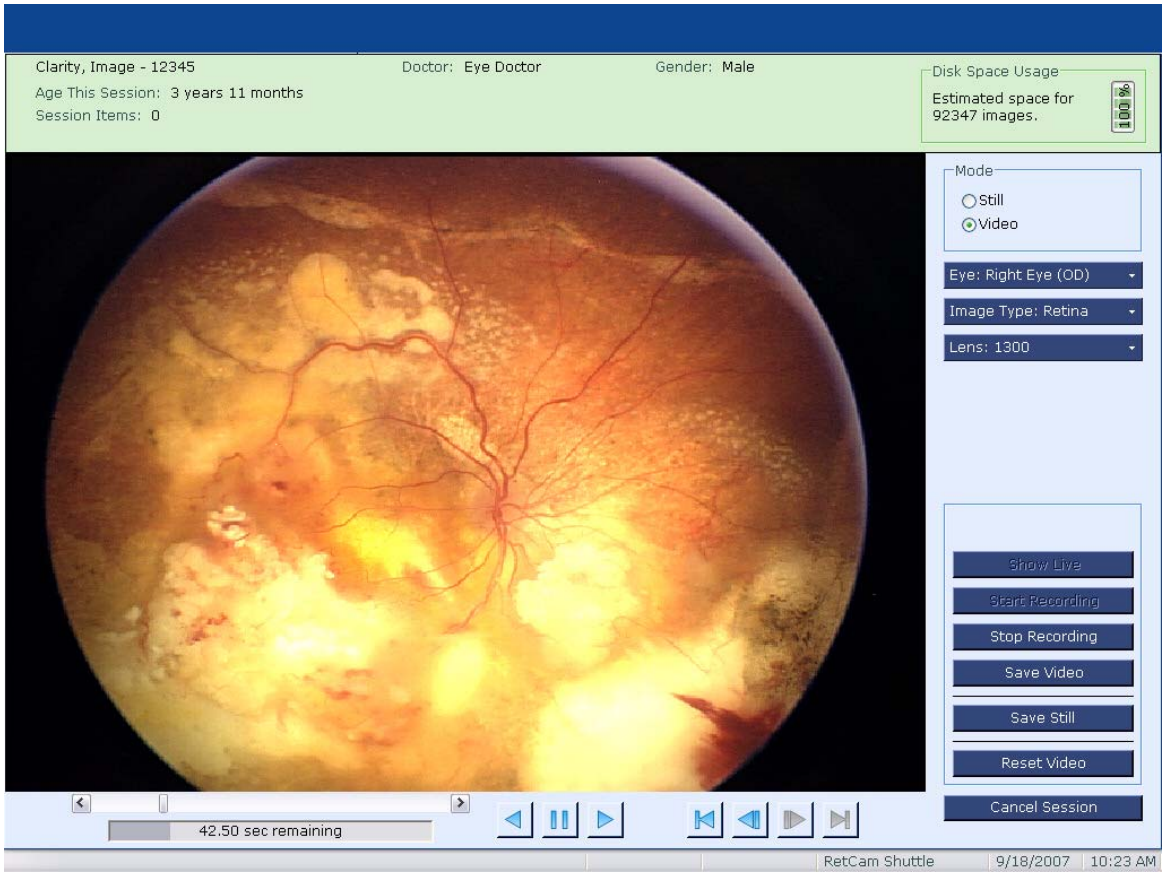


Figure 28 Live imaging screen (in video mode)

In video mode, the following buttons are available on screen:

- **Start Recording:** Starts recording video
- **Stop Recording:** Stops recording video
- **Save Still:** Saves a still image to the hard drive
- **Save Video:** Saves the recorded video to the notebook's FIFO buffer
- **Reset Video:** Erases the recorded video and prepares to start again
- **Cancel Session:** Ends the imaging session

☞ **Note: When you end a video session (by clicking Cancel Session) and then close the Add / View Session Notes dialog that automatically appears afterward, you will erase the video buffer, which means you can no longer replay the video nor capture additional stills from it. However, you will not erase any video clips or still images you already saved—you can view these in the Review screen.**

Recording Live Video and/or Saving Stills

In video mode, press the **Snap** button on the footswitch to start and stop live video recording. (The button toggles between start and stop.) When you pause the live video, you can click **Save Still** (or press **'S'** on the keyboard) to save the current image from the video clip.

As you record live video, the status bar displays recording time left in seconds.

Video Replay

When you stop live recording, the playback buttons are enabled.

Reverse, pause, and play

Go to the beginning of the recorded video

Go back one frame

Advance one frame

Go to the end of the recorded video

Tip: Using the left and right arrow keys on the keyboard will also move the video back or forward one frame at a time.

Saving Still Images During Video Replay

Video replay enables you to identify and save the optimal still images from the session. Follow the steps below to save still images during video replay:

Note: To save still images during video replay, you must first pause the video playback. Clicking Save Still or pressing 'S' on the keyboard will not save a still image during video replay.

1. Start playback by clicking **Play** or **Reverse** .
2. Click **Pause** when you see an image you want to save.
3. To find the most favorable video frame to save, click **Advance One Frame**

   or **Go Back One Frame** .

   You can choose from approximately 30 frames per second.
4. When the preferred image is displayed, click **Save Still** (or press **'S'** on the keyboard).
5. Click **Play** or **Reverse** to resume video replay and repeat the process, if desired.

Saving Video Clips

WARNING: Recall that the FIFO buffer on the notebook hard drive has limited capacity and when it becomes full, the oldest files are deleted to accommodate new images. Therefore, because video files are so large, saving video often can trigger deletion of files from the notebook's FIFO buffer. If deleted files are not backed up, they are lost permanently. For this reason, we do not recommend saving whole videos. Rather, we recommend saving still images from recorded video and then click Reset Video to delete it.

Note: Saving a 15 second video clip can take a minute or more. You cannot cancel saving once you begin. Saved video is compressed and stored in AVI format. You can no longer save still images from a video after it is saved.

When you click **Save Video**, a progress dialog asks you to wait and shows progress of saving.

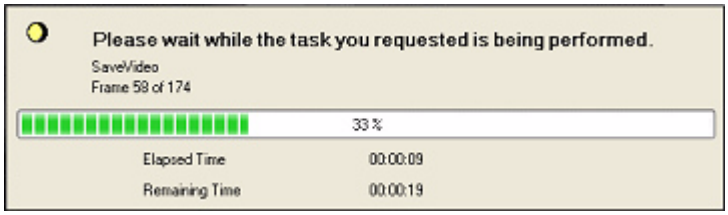


Figure 29 Save video in progress

The progress dialog displays the number of frames saved, the elapsed time and the time remaining.

Session Notes

When you exit live imaging, the Add / View Session Notes dialog appears. For each eye, it provides a field where you can type in notes.

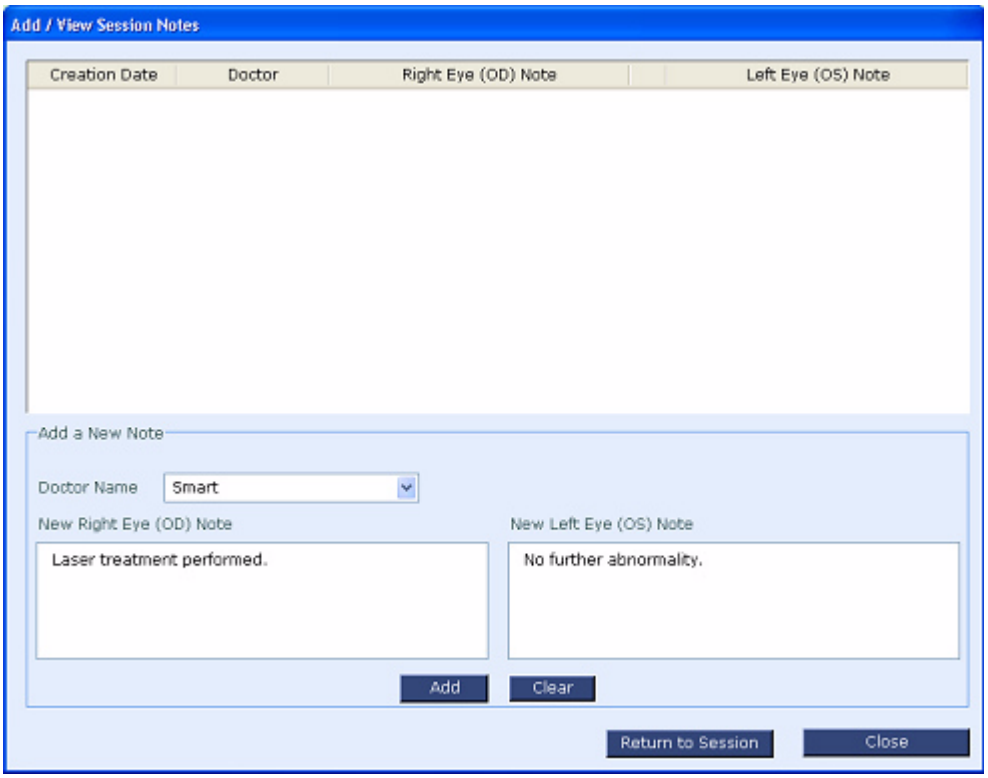


Figure 30 Add / View Session Notes dialog

The notes list field at the top tracks all notes entered by creation date, doctor and eye.

To add notes:

1. Type new notes in the fields titled New Right Eye (OD) Note and New Left Eye (OS) Note.
2. Click **Add** to add notes you have typed to the notes list above.
   - You cannot change a note after you click **Add**.
   - Click **Clear** to clear both fields before saving.
   - Click **Return to Session** to return to live imaging.
3. When finished, click on **Close** to close the window. The Review screen opens displaying the current patient and session just imaged.

You can add notes also from the Review screen. Once saved the text cannot be modified. You can append text to notes from the Review, Compare and Image Process tabs by clicking **Session Notes**. Notes are identified by date and the doctor's name.

4 Review and Compare Images

Having acquired images, they are available for review and comparison This section covers the following topics:

- Review Screen, below
- Compare Screen, page 59
- Printing, page 60

Review Screen

The Review screen appears automatically when you exit live imaging. You can also access it by clicking its tab or pressing F4 on the keyboard.

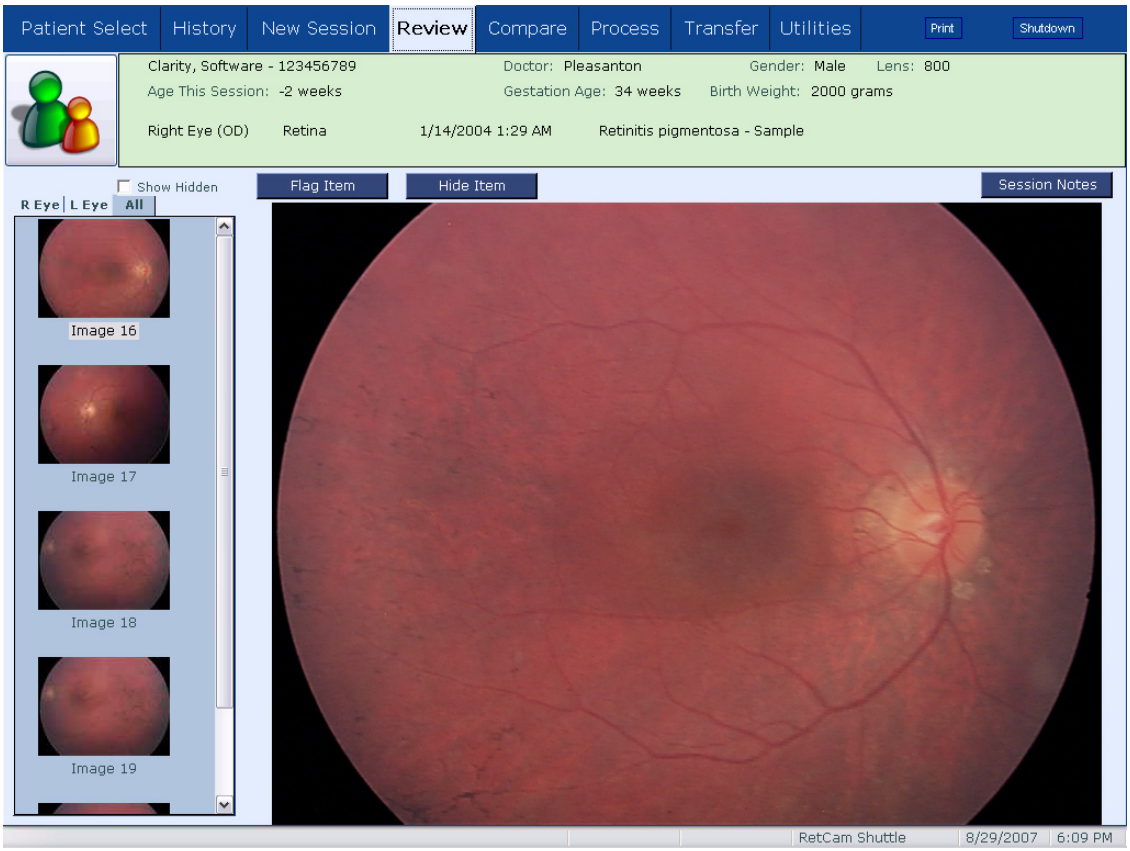


Figure 31 Review screen

When you exit live imaging, the Review screen displays the images acquired in the session just completed. When you access the Review Screen by other means, it displays the images for the last patient and session you selected. You can change the selection at any time using the Patient/Session Selector icon at upper left. (This icon appears on several screens and has similar functionality.) See Patient/Session Selector on page 46 for details on its use.

By default, thumbnails for all images acquired in the selected session appear along the left side. You can click on the tabs for R Eye, L Eye, or All above the thumbnails to display only right eye images, only left eye images, or all images from an imaging session.

The currently selected image (the first one by default) appears full size. Click on a thumbnail to display the full resolution image, or use the up and down arrow keys on the keyboard to select a thumbnail.

Thumbnails of video clips have a symbol indicating it is a video. Click on the thumbnail to bring the video to the display area. Video navigation buttons will then be visible and enabled. The buttons have the same functions as for live imaging. Click **Play** to start playing video.

The following options are available on the Review Screen:

Session Notes

Click **Session Notes** to review or append text to the session notes in the Review screen. You cannot alter saved notes. Notes are identified by date and the doctor's name.

Hide Item

Click **Hide Item** to hide the current image. Hidden items are not deleted. Their thumbnails do not appear unless the **Show Hidden** box above the All tab is checked.

Show Hidden

Default is unchecked. Only thumbnails of non-hidden images are listed. When checked, thumbnails for hidden images appear grayed out, signalling they are unavailable for full size viewing.

Unhide Item

When **Show Hidden** is checked and you click on the thumbnail of a hidden image, the **Hide Item** button toggles to **Unhide Item**, which you can click to make the image available again for full size viewing.

Flag Item

Click **Flag Item** to flag the current image as an image of special interest. A small red flag appears at the top left corner of the thumbnail. On the Transfer screen, there is a **Select Flagged** option you can use to select flagged items for transfer.

Unflag Item

When you click on the thumbnail of a flagged image, the **Flag Item** button toggles to **Unflag Item**, which you can click to remove the flag.

Print Image

Click **Print** to print the current image displayed.

Compare Screen

The Compare screen appears when you select its tab or press F5 on the keyboard. Use the Compare screen to compare any two images. You can compare among a patient's images, or between patients.

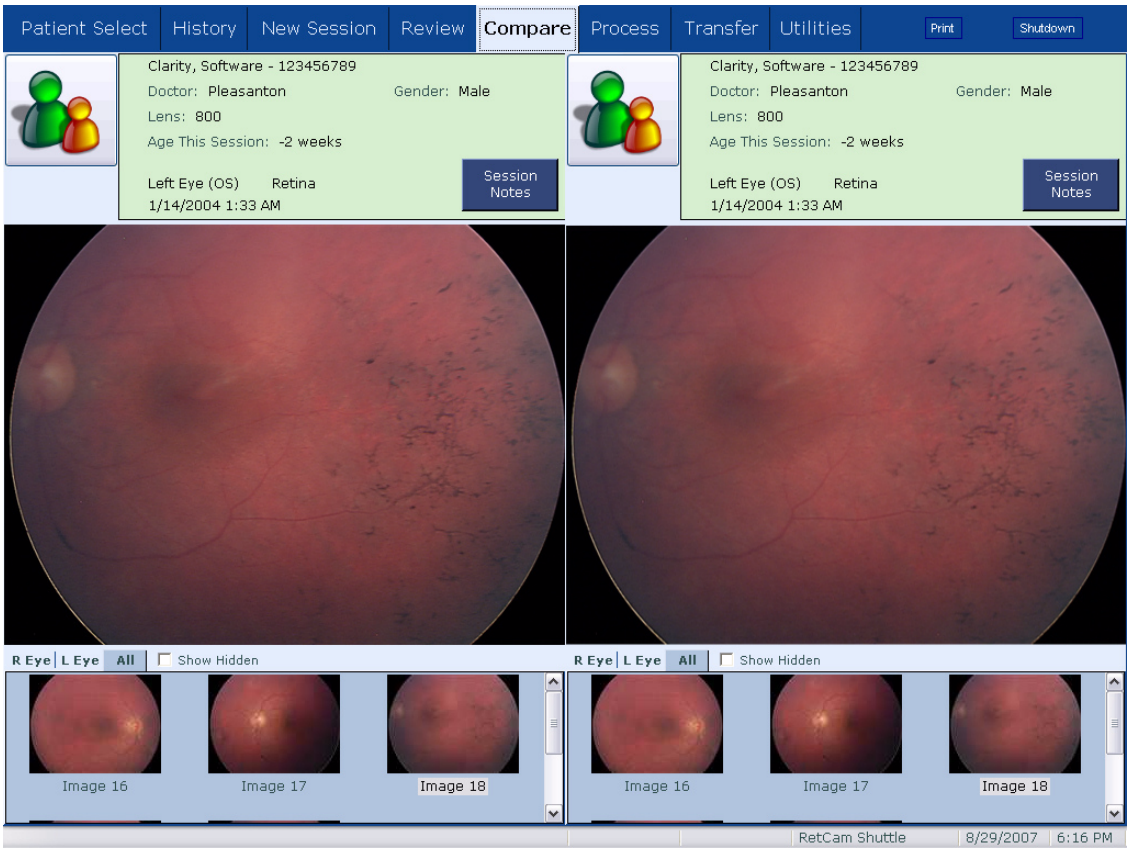


Figure 32 Compare [Images] screen

If you access the Compare screen from the Review screen, the last image displayed on the Review screen will appear on the left side of the Compare screen. On the right side, by default, the first image of the first session for the same patient appears. Identifying information for each image appears above it. Below each image at the bottom, thumbnails appear for all images in the same session.

Use the Patient/Session Selector above either or both images to change the patient and/or session on that side.

It is not possible to compare videos. **Hide Item** and **Flag Item** are not available from this screen.

Session Notes

Click **Session Notes** above the desired image to review or append text to the session notes for that image. You cannot alter saved notes. Notes are identified by date and the doctor's name.

Print Images

Click **Print** to print the two images displayed on this screen one on top of the other.

Printing

The **Print** button appears near the top right of screens when printing is available.

☞ **Note: Print is only available if there is a printer attached to the system, either directly or through the network, if so connected.**

WARNING: Never connect the RetCam Shuttle to a network or any externally powered devices or peripherals *during imaging*.

Printing Images

You can print images from the:

- **Review Screen:** Prints the single image currently displayed
- **Compare Screen:** Prints the two displayed images one above the other
- **Process Screen:** Prints the processed image currently displayed

For the image printer, the default paper size is set to 5" x 7". For optimal resolution, Clarity recommends printing images 5" x 7" or smaller. This also avoids the rapid depletion of printer ink.

Printing Reports

You can print reports from the:

- **Patient Select Screen:** Prints the displayed list of patients
- **History Screen:** Prints a detailed report for the selected patient.
  - Gives the option to print Patient History report or an ROP report

Reports are formatted to fit on US Letter or A4 paper.

Recommended Printers and Supplies

☞ **Note: Clarity recommends that you use only those printers that Clarity supplies with or has identified for use with the RetCam Shuttle. Clarity also sells printer supplies—photo paper and ink—for the printers it supports.**

It is possible to print using other printers not supplied by Clarity or not identified by Clarity for use with the RetCam Shuttle, but this is not recommended.

Set Default Image and Report Printers

The Utilities Screen enables you to select the default printer to be used for image printing and for report printing. See Printers on page 96 for details.

Include on Printout for Images

When printing images, the Include on Printout dialog appears first when you click **Print**. It gives you the option to include the name and patient ID on the image printout.

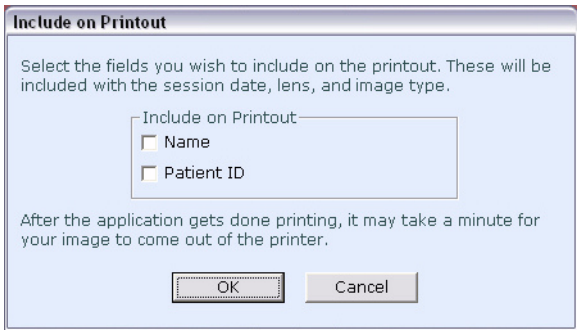

Include on Printout
Select the fields you wish to include on the printout. These will be included with the session date, lens, and image type.
Include on Printout
Name
Patient ID
After the application gets done printing, it may take a minute for your image to come out of the printer.
OK
Cancel

Figure 33 Include on Printout dialog for image printing

Select the desired checkboxes and click **OK** to proceed.

Print Information Dialog

The Print Information dialog appears each time you initiate a print operation. It gives you the option to select which printer to use, as well as the paper size.

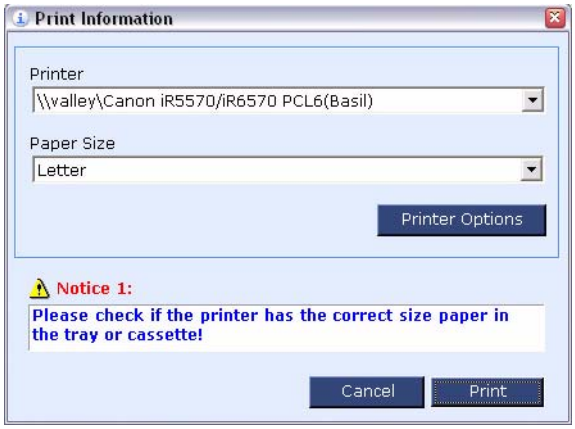


Figure 34 Sample Print Information dialog

The Printer and Paper Size fields display the default printer and paper size for printing either a report or an image, based on the screen from where you click **Print**. Use the Printer and Paper Size drop-lists to select from the available options. Be mindful to select the appropriate printer and paper size for printing either images or a report.

Print Information Notices

The Print Information dialog provides reminder messages based on your printer setup to help you use the correct paper size, since images and reports are intended to be printed on different sizes of paper. Report information will not fit on image-sized paper, and printing images on larger paper will use an unduly large amount of ink. The example below shows the two possible messages that may appear, depending on whether you are printing a report or an image, and whether or not you have separate printers selected for image and report printing.

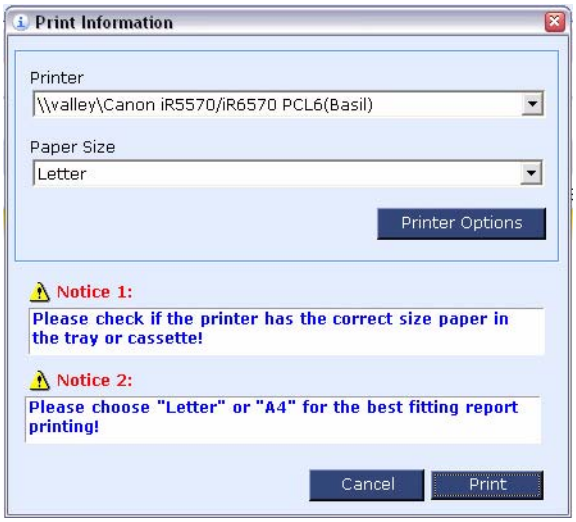


Figure 35 Sample Print Information dialog showing both possible messages

The two possible messages are:

- **Please check if the printer has the correct size paper in the tray or cassette!**
- **Please choose “Letter” or “A4” for the best fitting report printing!**

Printer Options

Click **Printer Options** to open the standard Print dialog, where you can adjust print options for this job, like number of copies, or access the printer Properties dialog.

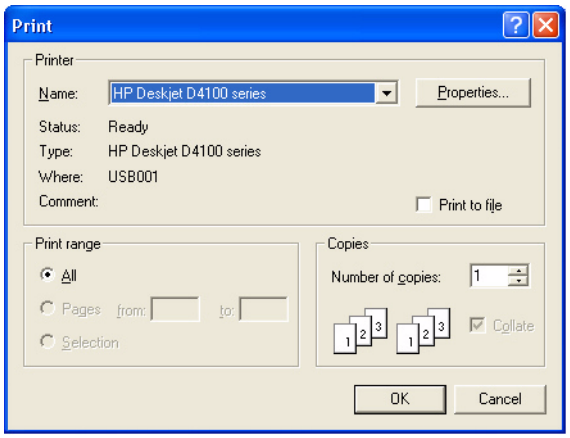


Figure 36 Standard Print dialog

Print

When you have made your selections and installed the correct paper (if necessary), click **Print** in the Print Information dialog to print the image or report.

5 Process Images

The Process screen enables you to perform image processing on saved images and then to save and export them in standard image formats for viewing on third-party systems.

☞ **Note: The original images in the database are never changed, even when you modify the image displayed on the screen. You can save processed images only outside the RetCam database and in a non-proprietary format.**

This section covers the following:

- Process Screen, below
  - Session Notes, page 65
  - Rotate 180º, page 65
  - Annotate Image, page 66
  - Adjust Image Display Parameters, page 67
  - Save (and Export) Processed Images, page 68

Process Screen

The Process screen appears when you select its tab or press F6 on the keyboard.

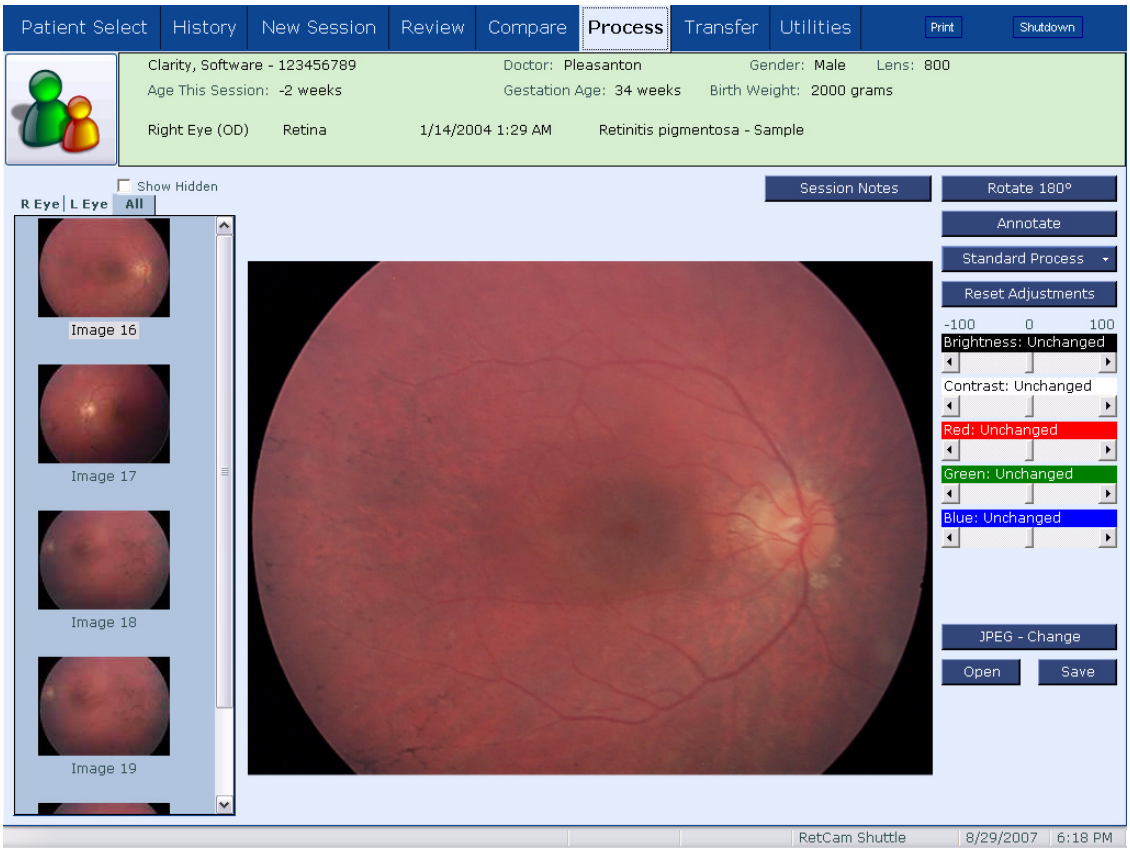


Figure 37 Process screen

Use the Process screen to perform image processing. You may often use the Process screen to prepare images for export, especially if you must export them using a standard image format like JPEG, BMP, or PNG. You can use the Process screen to save images in these formats in any accessible network location.

The layout of the Process screen is similar to the Review screen, with thumbnails for the currently selected session on the left and the currently selected image full size in the center.

On the right side, the screen provides following options, each of which is explained in more detail below:

- **View and append session notes**
- **Rotate an image 180º**
- **Annotate an image**
- **Adjust image display parameters: brightness, contrast and color**
- **Save and export images in standard image formats**

Session Notes

Click **Session Notes** to review or append text to the session notes in the Process screen. You cannot alter saved notes. Notes are identified by date and the doctor's name.

Rotate 180º

Click this button to rotate the image 180º.

Annotate Image

Annotate Image is useful to identify and provide information about images, especially when you intend to save them. The annotation text is overlaid on the image. Click the **Annotate** button to open the Annotate Image dialog.

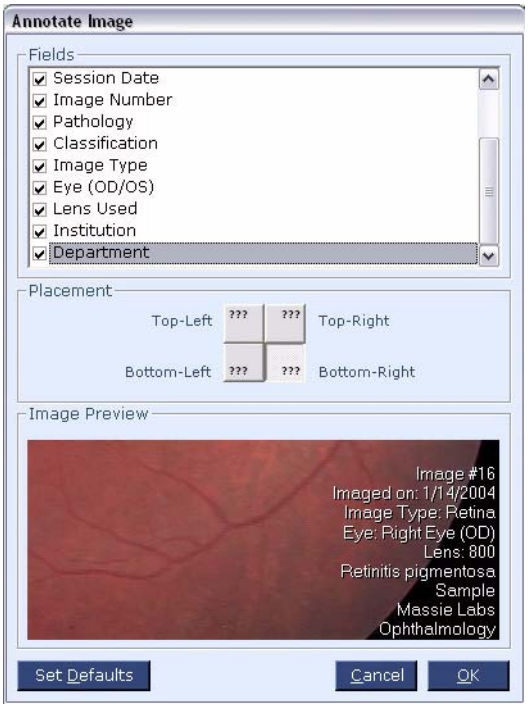


Figure 38 Annotate Image dialog

Annotation Fields

In the Annotation Fields list at the top, select the desired checkboxes to overlay the indicated information on the image. You can select checkboxes for the following items (scroll down to see all items):

- Patient ID
- Name
- Patient Initials
- Date of Birth
- Session Date
- Image Number
- Pathology
- Classification
- Image Type
- Eye (Right/Left)
- Lens Used
- Institution

- Department

Annotation Placement

In the Annotation Placement area in the middle of the dialog, click the desired button to select the corner of the image where the annotation will appear. Choose from:

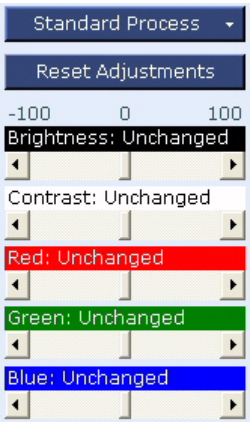
- **Top-Left**
- **Top-Right**
- **Bottom-Left**
- **Bottom-Right**

Image Preview

The annotations appear in the Image Preview pane for review before saving.

- Click **Set Defaults** to set the current selection of annotation fields and placement as the default.
- Click **Save** to save all your annotation selections.
- Click **Cancel** to quit annotation without saving your changes.

The annotations you select will remain on the Process Image display until you change the selection.



Adjust Image Display Parameters

The right side of the Process screen provides controls to adjust the following image display parameters:

- **Brightness**
- **Contrast**
- **Red**
- **Green**
- **Blue**

All parameters have a default setting of zero (0), and range from -100 to +100

- Each click on the right or left arrow at the end of the slider bar changes the parameter value by 1%.
- Each click on the bar to the right or left of the slider changes the parameter value by 10%.

Standard Process Button

The **Standard Process** button enables you to either apply the currently saved display settings to the image, or to save the new display adjustments you have made. When you click **Standard Process**, a dropdown menu gives you two choices:

- **Apply Saved Settings**: Applies the currently saved settings for **Brightness, Contrast** and **Red, Green and Blue**. Image display adjustments are applied to

all images in the current image processing session, until you save new settings or click the **Reset Adjustments** button, which resets all parameters to zero.

- When you leave the current session, the display settings are reset to zero.

- **Save Current Settings**: Saves the current settings for **Brightness, Contrast** and **Red, Green** and **Blue**. Now the settings can be applied when you select **Apply Saved Settings**.

Reset Adjustments Button

Click **Reset Adjustments** to reset all display parameters to zero.

☞ **Note: Images you save from the Process screen will reflect image display adjustments (and all other changes) you make, but the original images in the database will not be changed.**

Print Image

Click **Print** to print the current image, processed or not.

Save (and Export) Processed Images

You can use the Process screen to save images in the standard JPEG, BMP and PNG formats in any accessible network location. The group of three buttons at lower right enable you to access images from and save images to these locations. (When you save to removable media or a network location, you are in effect exporting the images there.)

- The '**XXX**' **– Change** button (where **'XXX'** stands for the current format: **JPEG - Change** in the example) enables you to change the file format in which images are saved.
- The **Open** button opens image files from outside the RetCam Shuttle database for processing.
- The **Save** button saves (and exports) image files to the location you choose.

Each of these functions is explained in more detail below.

Open an Image from Outside the RetCam Database

The **Open** button at lower right enables you to open images from outside the RetCam Shuttle database for processing. When you click **Open**, the Open Image dialog appears.

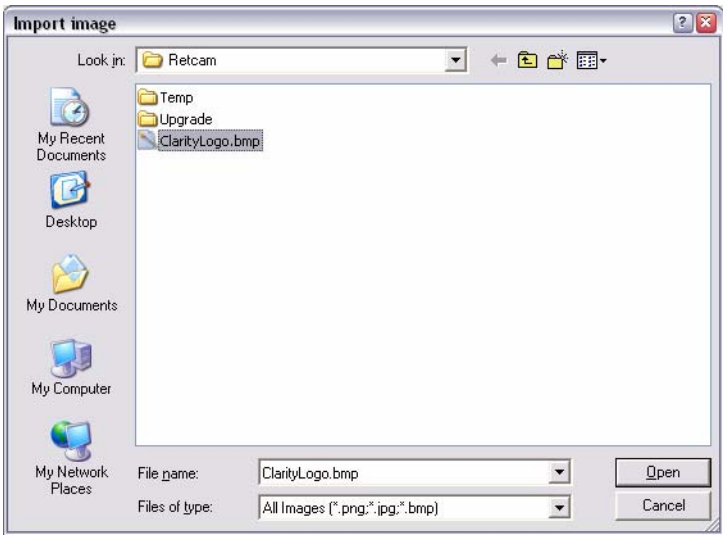


Figure 39 Import (open) Image dialog

This is a standard Windows dialog that enables you to find and open JPG, PNG and BMP image files (but not those in the proprietary RetCam format). You can select image files from any accessible location.

Change the Format for Saving Images

The **'XXX' – Change** button (where **'XXX'** stands for the current format: **JPEG - Change** in the example) enables you to change the file format in which images are saved.

To change the image format in which you will save an image:

1. Click **'XXX' – Change.** The Export Options dialog appears.

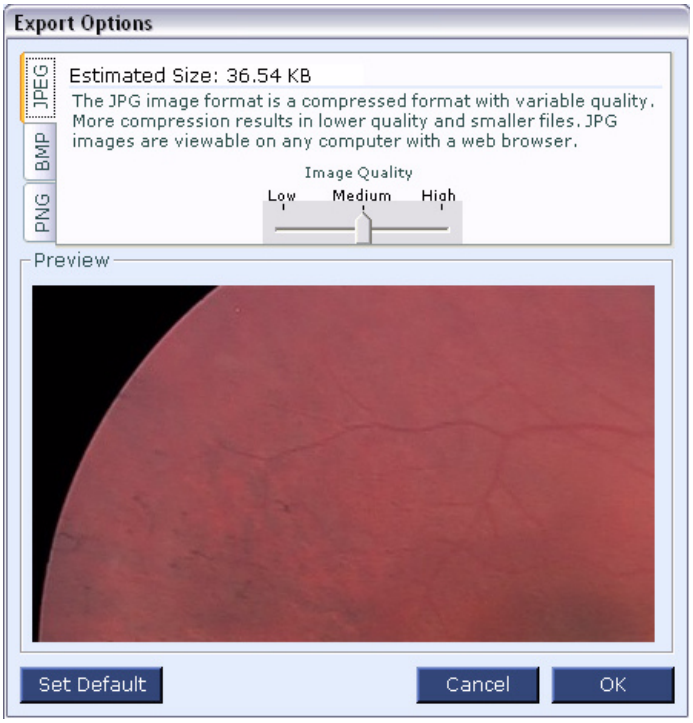


Figure 40 Export Options dialog

You can select from the following image formats:

- BMP: The bitmap format saves images at full resolution without any quality loss. It results in the largest files.
- JPEG (JPG): This format uses compression to reduce file size, which results in loss of quality in proportion to the amount of compression. Select the image quality before you save.
- PNG: Portable Network Graphic is a newer format which uses compression to reduce size (about half the size of a bitmap), but without loss in quality or resolution. It can be viewed in a standard web browser and used in image processing or viewing applications.

2. Click the desired tab to select JPEG, BMP, or PNG.

- If desired, click **Set Default** to make the current selection the default format each time you save an image from the Process screen.

3. Click **OK** to save your choice.

Save and Export an Image

You can save one image at a time. To save the current image, processed or not:

1. Click **Save.** The Export to image dialog appears.

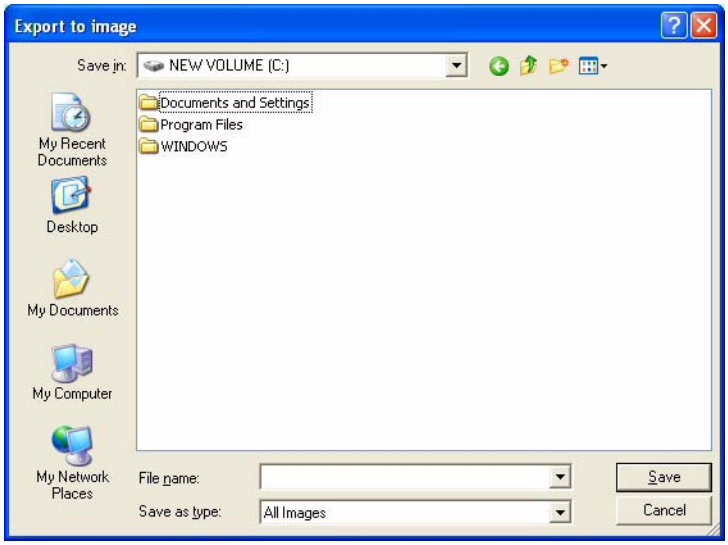


Figure 41 Export to image dialog

This is a standard Windows dialog that enables you to find and select the location where you will save the image file. You can select any location on the hard drive, on a connected network location, or on removable media.

2. Find the desired location where you want to save the image.

- If necessary, use the up-folder icon to the right of the address field to go up to higher levels of the drive or device directory.

- To create a new folder where you will save the image, click on the new folder icon. Type in the name of the new folder, such as “Smith 03-24-05”.

3. In the File Name field, enter the name of the image file you will save.
   - The file extension (.jpg, .bmp, or .png) is added automatically according to the format selected in the Export Options dialog.
4. Click **Save** to save the file.

6 Data Transfer

Data transfer means copying RetCam data (including patient data and/or images) to a new location (network, removable media, etc.). Data transfer occurs in two steps: export and import, both from the Transfer screen.

You can transfer data to any accessible and writable location. This chapter explains the purposes of data transfer and how to perform it. It covers the following topics:

- Purposes: Sharing and Backup, page 72
- Transfer Screen, page 74
- Export, page 75
- Import, page 82
- Networking a RetCam Shuttle, page 85

Purposes: Sharing and Backup

Data transfer has four purposes:

1. To make RetCam data available on other RetCam stations, which include both RetCam II and RetCam Shuttle systems and PCs running RetCam Review Software.
2. To implement data backup, that is, to make a backup copy of the original image data kept on the FIFO buffer of your hard drive.
3. To export for viewing with standard image software.
4. To import to third party imaging systems.

WARNING: Permanent data loss is possible if no backup solution is employed.

Recall that the RetCam Shuttle does not automatically make a backup copy when you acquire new images. Images are stored only on the hard drive of the computer, so removal of data becomes an absolute necessity to avert the possibility of data loss due to loss of the computer. It is the responsibility of the user to preserve data from permanent loss due to computer loss, theft, or failure of the computer by making appropriate backup copies.

Backup Recommendation: Network or Removable USB Mass Storage Device

☞ **Note: Consult your network administrator or an information technology professional regarding arrangements to implement a secure long-term data backup scheme in your particular situation. For details, see Networking a RetCam Shuttle on page 85.**

☞ **Recommended Backup Frequency: Each day you acquire new images.**

Recommended Backup Scenarios

Scenario 1: To a Network Server

In this scenario, you use data transfer to backup data to another computer on your office network, preferably a server-class computer with large and expandable capacity and internal backup functionality. The server must be Windows network compatible, which most servers are. See Networking a RetCam Shuttle on page 85 for instructions to link a RetCam system to the office network.

Scenario 2: To a Removable USB Mass Storage Device

Removable USB mass storage devices can have very large capacity for secondary backup. When not connected to the Shuttle notebook, keep the removable USB mass storage device in a secure place.

Recommended Scenario for Multiple RetCam Systems

In the situation where an institution has multiple RetCam systems, we recommend that you link each system to your office network and back up every system to the same backup folder on the network. See Networking a RetCam Shuttle on page 85 for instructions to link a RetCam system to the office network. When you backup in this scenario, we recommend you follow these tips:

- Clear the **Create subfolder** checkbox (see page 78 and associated tips).
- Select the **Organize patients into subfolders** checkbox (see page 79 and associated tips).

In this way, you will create a single shared repository for all patients accessible to all RetCam systems, and avoid creation of multiple patient records for the same patient. Each patient will have a separate subfolder in the backup folder, made up of last name, first name and patient ID, as in the example **Sayers, Gale.12345**. When you wish to extend the record of a patient not created on the current system, go to the backup folder and import the images from the patient subfolder of the desired patient.

Transfer Screen

The Transfer screen appears when you select its tab or press F7 on the keyboard.

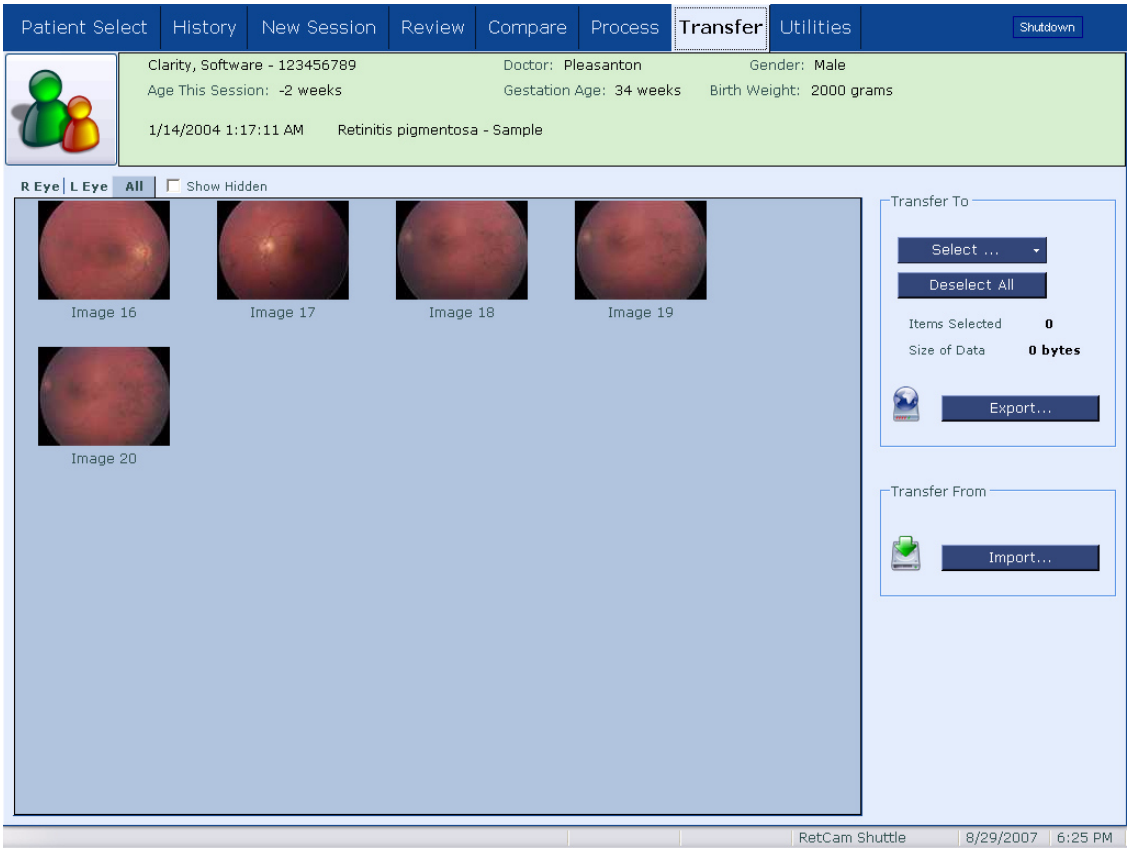


Figure 42 Transfer screen

Use the Transfer screen to perform data transfer, both export and import. When it opens, most of the screen displays thumbnails for the current session of the selected patient. **R Eye**, **L Eye** and **All** tabs and the **Show Hidden** checkbox appear above the images at left, with All shown by default. These enable you to display only right or left eye images and whether to display hidden items (not shown by default). On the right, the Transfer To area includes the **Select...** drop-list, and the **Deselect All** and **Export** buttons; the Transfer From area provides the **Import** button.

The current patient and session information appear as usual at the top. You can change the selection at any time using the Patient/Session Selector icon at upper left. See Patient/Session Selector on page 46 for details on its use.

Export

You can export data to any accessible location. There are three general steps to complete export, with several options within each one:

1. Select Images for Export, below
2. Select Export Options, page 77
3. Complete Export, page 81

WARNING: Never connect the RetCam Shuttle to a network or any externally powered devices or peripherals *during imaging*.

Select Images for Export

Note Regarding Export Size Capacity

You can use the system while export is ongoing as long as the number of images selected for export is less than 10,000. While you cannot directly select a specific number of images for export, you can be confident of exporting less than 10,000 images by exporting saved images in three month blocks. To do this, first go to the Patient Select Screen (see page 39) and perform a Search by Date range (see page 42), specifying a three month block. Then, back in the Data Transfer Screen, click the Select ... button and choose Search Result (Using Patient Select options).

To select images for transfer, follow these steps:

1. Click on a thumbnail to select the image. To select multiple items, click and drag over multiple contiguous items, or hold down the **Ctrl** key and click (Ctrl-click) on individual items. Selected items are highlighted.

   To select items in pre-defined groups, use the **Select...** button; its options are described below.

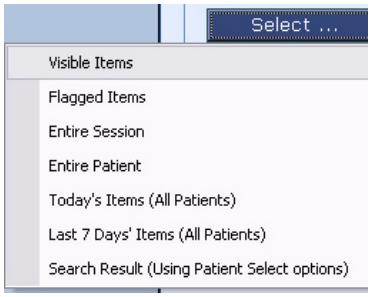


Figure 43 Select drop-list

Tip: The options you select under the **Select...** button are additive. To make sure you select only the single option desired, first click the **Deselect All** button before you use the **Select...** button.

Tip for Backup: The **Select...** button is particularly useful if you are performing a regular data backup. For example, if you back up items daily, you would select **Today's Items (All Patients)**; if you back up weekly, you would select **Last 7 Days' Items (All Patients)**.

- **Visible Items:** Selects all images currently displayed. Selects all right eye items in this session if the R Eye tab is selected. Selects all left eye items in this session if the L Eye tab is selected. Selects all items in this session if the All tab is selected.

Visible Items does not select hidden items unless the **Show Hidden** checkbox is selected.

- **Flagged Items:** Selects all flagged images in this session.
- **Entire Session:** Selects all images in this session.
- **Entire Patient:** Selects all images in all sessions for this patient.
- **Today's Items:** Selects all images acquired on today's date.
- **Last 7 Days' Items:** Selects all images acquired on today's date and the six previous dates.
- **Search Result (Using Patient Select options):** Selects all images from all patients found in the last search result.

Tip for Backup: To perform a full backup, first search in the Patient Select screen with all search fields blank, so the search returns all patients in the database. Then in the Transfer screen, select **Search Result (Using Patient Select options)** in the **Select...** drop-list. This will result in all images for all patients being exported to the backup destination.

You can click **Deselect All** at any time to clear all selections and start over.

2. When you have selected the desired items for export, click **Export**. The Export Items To dialog appears.

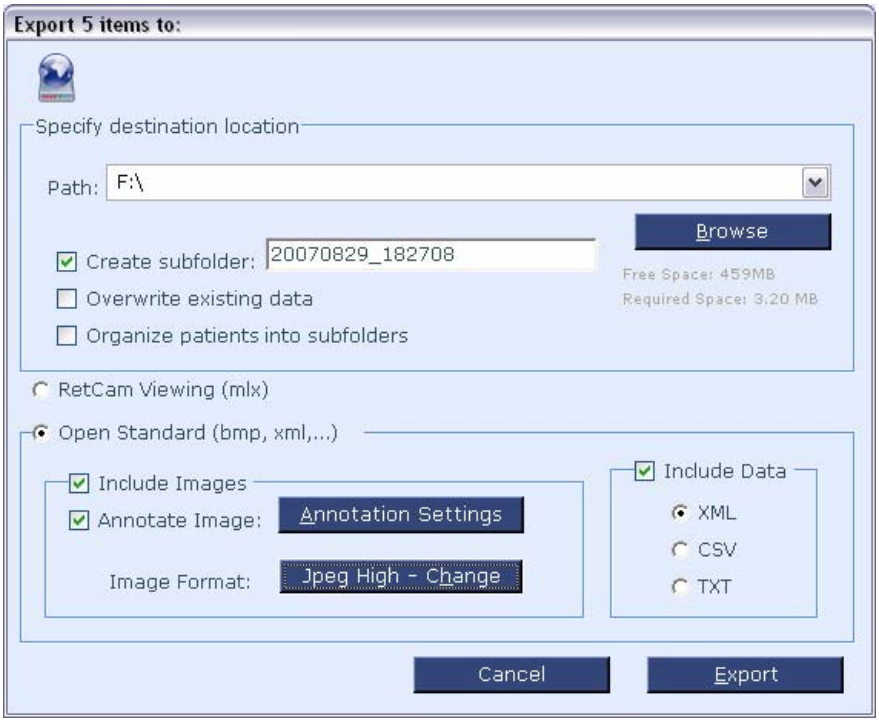


Figure 44 Export Items To dialog

The title bar of the dialog includes the number of items selected for export, 5 in the example shown. By default, it shows the path and all the options last used.

Select Export Options

Use the Export items to dialog to specify where to export the images, the image format and what information to include with the images.

Specify Destination Location

3. In the Specify Destination Location area near the bottom of the Export Images To dialog, the Path field indicates the path where the export folder(s) will be created.

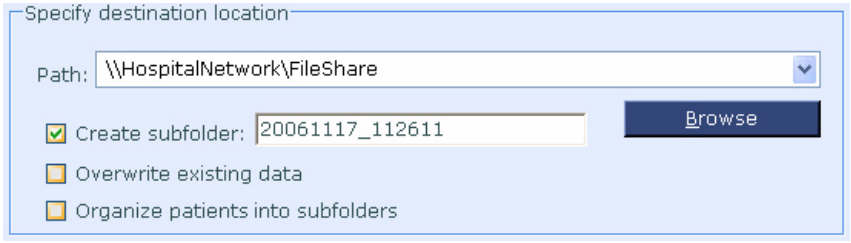


Figure 45 Specify Destination Location area

By default, the Path field shows the path last used. To change the path, click **Browse**. A standard Windows Browse dialog opens, enabling you to find and select the desired export path, which may be any accessible network location.

Tip for Backup: Create a separate destination location the first time you transfer data for backup purposes. Then, when performing routine data backup, always select the same path for backup. Also, make sure the **Create subfolder** checkbox is clear and the **Organize patients into subfolders** checkbox is selected. For details, see the Tip for Backup under the Create Subfolder Checkbox on page 78.

Note: For simplicity in performing data transfer and finding exported files, we recommend you use a single destination location for all export operations, except that you should use a separate location for backup. To distinguish exported files, you can use the Create Subfolder Checkbox, the use of which is explained on page 78.

Note: If exporting to a network location, the system must be connected to the network to see it in the Browse dialog. If using removable media, check the amount of space available to make sure there is enough room before you export. The size of data (in MB) selected for export appears in the Transfer To area of the Transfer screen.

4. In the Browse dialog, find the location where you want to export the files and click **Open**. The path will be automatically entered in the Path field.

- If necessary, use the up-folder icon to the right of the address field to go up to higher levels of the drive or device directory.

- To create a new folder where you will export the image, click on the new folder icon. Type in the name of the new folder, such as “Smith 03-24-05”. The folder must be shared with write permission.

Tip 1 for Network Data Transfer: The first time you specify the destination location, in the Browse dialog, look for the desired target server by selecting **My Network Places > Entire Network > Microsoft Windows Network > [computer name] > [standard export folder],** where [computer name] is the name of the desired target computer on the network and [standard export folder] is a folder in its root directory where you will regularly export files. The target computer may be a server or another RetCam station.

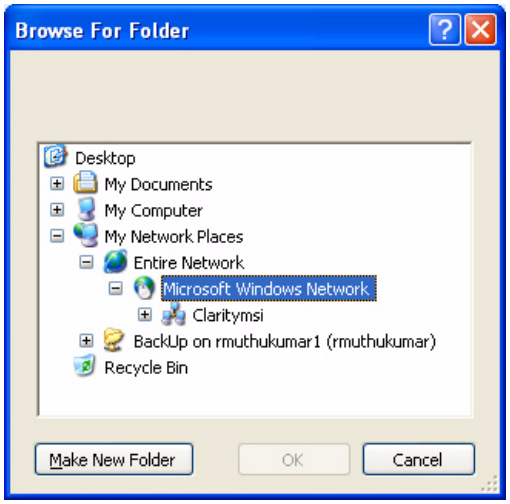


Figure 46 Finding the export destination on the network

Tip 2 for Network Data Transfer: When using a network location for export, use the same export destination folder each time (and for all attached RetCam systems) and give it a recognizable name, like **FileShare**. This will simplify finding the folder from which you will import images to other systems.

Tip 3 for Network Data Transfer: To access the export destination folder, it must be shared. To share a folder on the target computer, from that computer, locate the desired folder to share using Windows Explorer. Right-click the folder and select **Sharing.** In the Sharing tab of the folder Properties dialog, select the options to share the folder.

Create Subfolder Checkbox

Select the **Create subfolder** checkbox to create a subfolder for the exported files within the default export path. The system automatically generates a unique name for the subfolder composed of the current date and time. To provide the name with a more recognizable meaning, for example, a patient name, you may add text to it, retaining the unique date and time, or change it completely.

Tip for Backup: When performing routine backup to the backup location, make sure you select the **RetCam Viewing (mIx)** radio button so you save the images in a format accessible by a RetCam system. Then clear the **Create subfolder** checkbox and select the **Organize patients into subfolders** checkbox. When you export, the system will create a subfolder for each patient whose images are exported. The name of each patient subfolder is composed of last name, first name and patient ID, for example: Wingate, David.12345. If the **Create subfolder** checkbox is cleared, you have created a condition where routine backup results in one recognizable folder for each patient being present in the backup location. If the **Create subfolder** checkbox is selected, each incremental backup will create its own subfolder, and files for the same patient will be scattered over many export subfolders.

Tip for Export of a Few Images: When exporting not for backup purposes but to share a few images from one or a few patients with another RetCam system, use the standard destination location but select the **Create subfolde**r checkbox and give the export subfolder a highly recognizable name. This way the export subfolder will be easy to find in the usual directory but with a clearly purposeful name. (Also make sure you select the **RetCam Viewing (mIx)** radio button so you save the images in a format accessible by a RetCam system.)

Overwrite existing data checkbox

This option is to be used only when you wish to replace files previously exported to the same destination. Select this checkbox to overwrite existing records. If not selected, duplicate data will not be exported again. This speeds export by exporting only new data. When performing routine backup, you normally want to have this checkbox clear so that only new data is exported, saving time and making backup incremental.

Organize patients into subfolders checkbox

Select this option to create a subfolder for each patient whose images are exported. When you export, the system will create a subfolder for each patient whose images are exported. The name of each patient subfolder is composed of last name, first name and patient ID, for example: Wingate, David.12345. This is especially useful for incremental backup as described in the Tip for Backup on page 79.

Select Image Format

5. Select either **RetCam Viewing (mlx)** or **Open Standard** format for export.

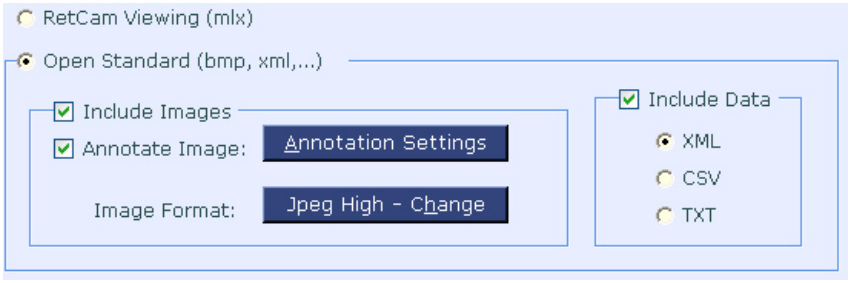


Figure 47 Selecting the format for export

- **RetCam Viewing:** This radio button is selected by default. (MLX is the proprietary RetCam image format.) Use this option for routine data backup and to share data with other RetCam stations, which include both RetCam II and RetCam Shuttle systems, and PCs running RetCam Review Software or the Clarity Viewer program.

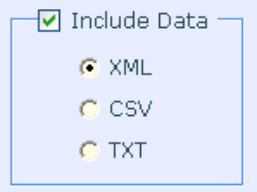
☞ **Note: RetCam systems can read only native RetCam data files, which are in the MLX format. MLX files include images and patient data. Images exported in standard formats (JPG, PNG or BMP) do not have any patient data associated with them.**

- **Open Standard:** Select this radio button to export image data in the standard (non-proprietary) formats (JPG, BMP or PNG). If you select this radio button, its further options become available.
  - **XXX - Change button: Click XXX - Change** (where **'XXX'** stands for the current format: **JPEG High - Change** in the example) to change the image format for export. The Export Options dialog appears (see Figure 40 on page 70). You can select from the following image formats:
    - BMP: The bitmap format saves images at full resolution without any quality loss. It results in the largest files.
    - JPEG (JPG): This format uses compression to reduce file size, which results in loss of resolution or quality in proportion to the amount of compression. You can select the image quality before you save.
    - PNG: Portable Network Graphic is a newer format which uses compression to reduce size (about half the size of a bitmap), but without loss in quality or resolution. It can be viewed in a standard web browser and used in image processing or viewing applications.

    Video clips are always saved and exported in AVI format.
  - **Include Images checkbox:** Select this checkbox to include image data in the standard (non-proprietary) formats (JPG, BMP or PNG).

- **Annotate Image checkbox:** Select this checkbox to include image annotations on all images you export. (Videos are not annotated.) When selected, the **Annotation Settings** button becomes available. When you click **Annotation Settings**, the Annotate Image dialog opens. For further instructions, see Annotate Image on page 66.

☞ **Note: You must clear all annotation checkboxes to exclude all annotations from the exported images. Clearing the Annotate Image checkbox does not ensure that no annotations will be exported.**



- **Include Data checkbox:** Select this to export the patient data associated with each image, which includes all the data entered on the Patient Information dialog (see Figure 20 on page 43). When selected, you can further select the format from among XML (extensible markup language format), CSV (comma separated values format), and TXT (generic text format). This option is offered to facilitate transfer of patient data with standard-format images to a PACS system (picture archiving and communications system).

Complete Export

6. Click **Export** to export the files to the specified destination.
   - Click **Cancel** to cancel the export before completion.

When you click **Export**, a dialog opens to show export progress.

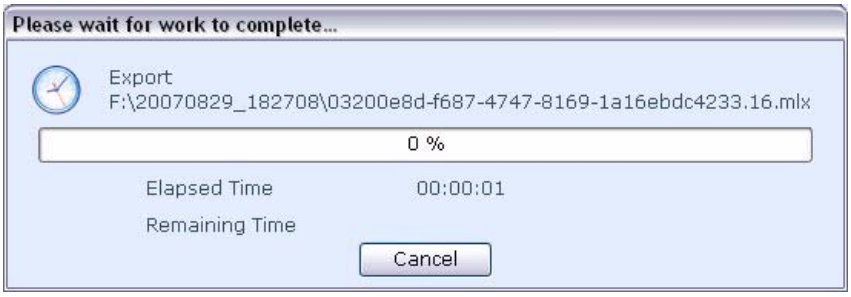


Figure 48 Export progress dialog

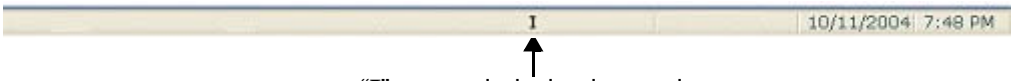
When export is complete, an Export Report dialog provides a summary.

Figure 49 Export successful

If not all the selected items were exported, the Details pane explains why. It could be because some files are duplicates (already present in the destination directory), or the export file is not found, or it is corrupt, or the destination is write-protected, or there is not enough space on the destination disk or media.

Indexing Delay

☞ **Note: If an installed removable media already has data on it, the system may need to index the data before export. When indexing, an "I" appears in the status bar along the bottom of the screen.**



"I" means indexing is ongoing

During indexing, system functions may be a little slow, and the system will complete indexing before initiating the export. In this case, it may take a while for the export to complete.

☞ **Note: Automatic indexing is off by default. To turn on automatic indexing, go to the Utilities screen and select the Auto Index External Media Checkbox — see page 97.**

Import

Except for data backup, the export destination on the network is an intermediate location. To complete the data transfer and make the images available for viewing on another RetCam system, you must use the RetCam software to import the transferred images into the target system database.

☞ **Note: We recommend that you do not import more than 15,000 images in one import operation because it may take a long time. One way to be sure is to**

import only the files from a folder to which you (or someone else) exported a limited number of images. In general, we recommend you import images from one patient at a time, as described in the Recommended Scenario for Multiple RetCam Systems on page 73.

Follow these steps to import RetCam images:

1. On the Transfer screen, click **Import**. The Import Folder dialog appears.

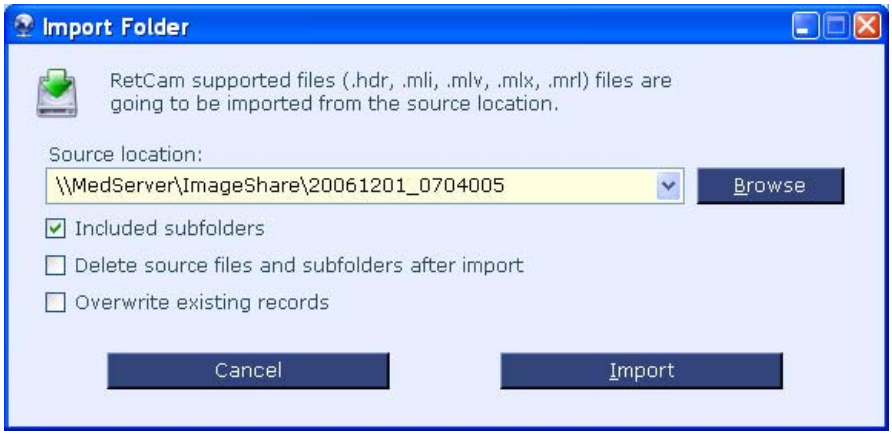


Figure 50 Import Folder dialog

By default, it shows the Source location path and all the options last used.

Note: If you follow the recommendations here, importing from a single patient subfolder in the main export or backup folder each time, you will find the desired patient subfolder in the same path, but have to browse to select the specific, desired patient subfolder.

2. To change the source location, click **Browse**. A standard Browse dialog appears, open to the last import folder used.

Tip for Network Import: The first time you specify the source location for network import, in the Browse dialog, look for the source server by selecting **My Network Places > Entire Network > Microsoft Windows Network > [computer name] > [standard export folder],** where [computer name] is the name of the source computer and [standard export folder] is a folder in the root directory where you regularly export files. The source computer may be a server or another RetCam station.

3. In the Browse dialog, find the location from where you want to import files and click **Open**. The path will be automatically entered in the Source location field.

- If necessary, use the up-folder icon to the right of the address field to go up to higher levels of the drive or device directory.

Included subfolders checkbox

Select this checkbox if you want to import images in all subfolders of the source location. If not selected, you will import only the files found in the source location folder itself, and no images in its subfolders. If you want files from a specific (patient) subfolder only, select that subfolder in the Browse dialog.

Delete source files and subfolders after import checkbox

To manage the size of the export destination, select this checkbox to delete the source files and subfolders after import is complete.

☞ **Note: Do not select this checkbox if you or others want to import the same data to another RetCam station, which would be the case especially if you are importing from the backup repository.**

☞ **Note: This does not affect any working RetCam database, but only the intermediate location where files are exported to and imported from.**

Overwrite existing records checkbox

This option is to be used only when you wish to replace previously existing files. Select this checkbox to overwrite existing records. If not selected, duplicate records will not be imported.

4. After selecting the desired options, click **Import.** A dialog opens to show import progress.

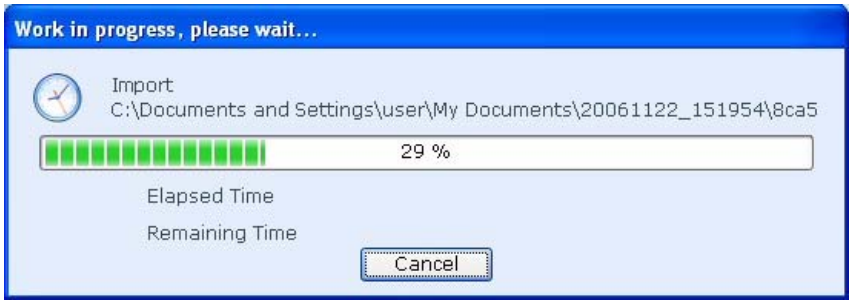


Figure 51 Import progress dialog

When import is complete, an Import Report dialog provides a summary.

Figure 52 Import successful

If not all the items were imported, the details pane explains why. It could be because some files are duplicates (already present in the destination database), or the file is not found, or it is corrupt. A sample report with error messaging appears below.

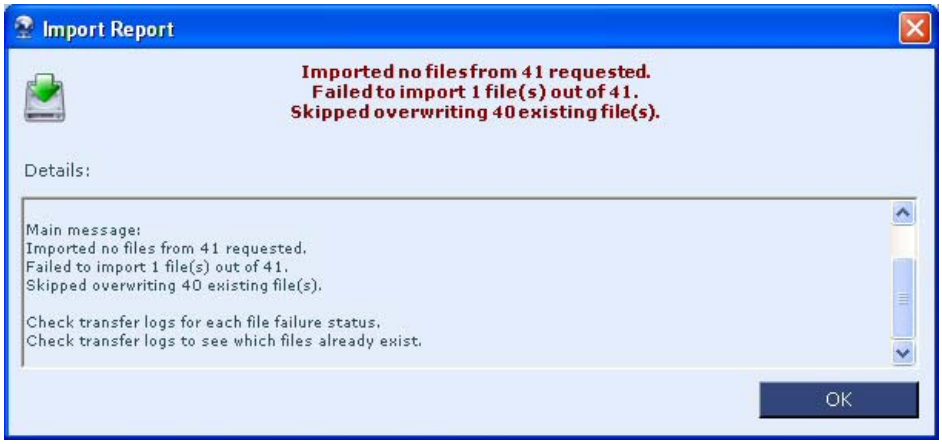

Import Report
Imported no files from 41 requested.
Failed to import 1 file(s) out of 41.
Skipped overwriting 40 existing file(s).
Details:
Main message:
Imported no files from 41 requested.
Failed to import 1 file(s) out of 41.
Skipped overwriting 40 existing file(s).
Check transfer logs for each file failure status.
Check transfer logs to see which files already exist.
OK

Figure 53 Import Report dialog

Successfully imported files go into the local database and are available immediately in the patient list. The original identifying information always remains associated with the images, so you can determine their source.

Networking a RetCam Shuttle

If you wish to exchange data to and from other RetCam stations (which may be other RetCam II or Shuttle systems or RetCam Review Station computers), the information in this section will help you accomplish this.

☞ **Note: Due to the variations possible in network configuration, the knowledge of which is important to successfully add systems to a network, Clarity**

recommends that networking be left to a network specialist who is familiar with the configuration of your local network.

Configuring Permanent Access to Network File Shares

The following information is intended to be understood and implemented by a network specialist familiar with your local network.

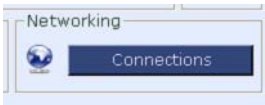
A network file share is a shared (accessible) folder in a network location (on a server). This section explains how to configure access to a Windows network file share by a RetCam device that is not part of the domain to which the server belongs.

☞ **Note: A system administrator (network specialist) must assign a user account on the domain to access the network file share to be used for network data transfer with write access. We suggest you create a separate folder on the server for storage of RetCam images.**

Add A Network Place

Follow the steps below to add a network place, which will give the RetCam device permanent access to the network file share for data transfer operations relative to the access of the user account used.

☞ **Note: There is no limit to the number of network places which can be added.**



1. Click the **Connections** button in the Utilities Screen (see page 95) to open the Network Connections dialog.

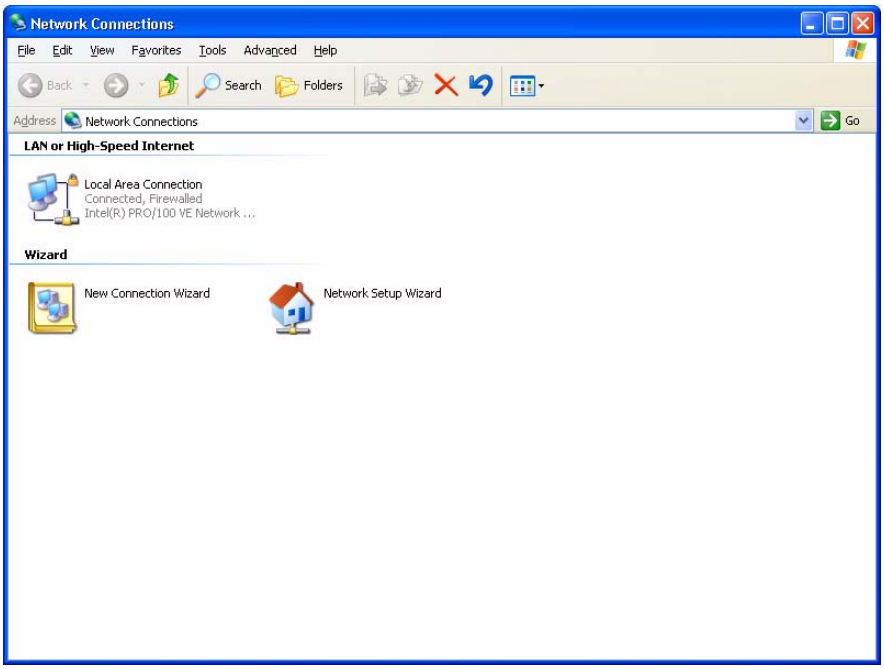


Figure 54 Network Connections dialog

2. Select **Map Network Drive** from the **Tools** menu (click **Tools >Map Network Drive…**). The Map Network Drive dialog appears.

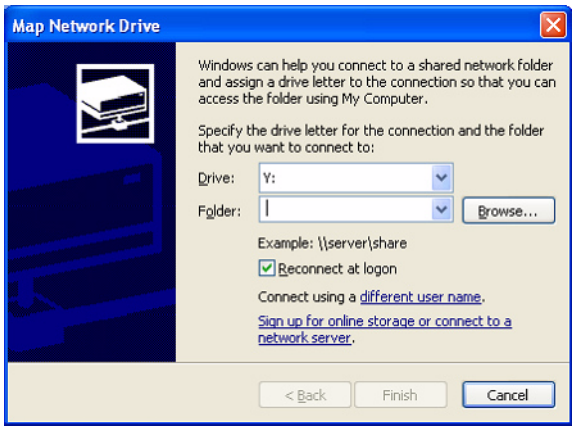

Map Network Drive
Windows can help you connect to a shared network folder and assign a drive letter to the connection so that you can access the folder using My Computer.
Specify the drive letter for the connection and the folder that you want to connect to:
Drive:
Y:
Folder:
Browse...
Example: \\server\share
Reconnect at logon
Connect using a different user name.
Sign up for online storage or connect to a network server.
< Back
Finish
Cancel

Figure 55 Map Network Drive dialog

3. Near the bottom of the dialog, click **Sign up for online storage or connect to a network server.** The Add Network Place Wizard appears.

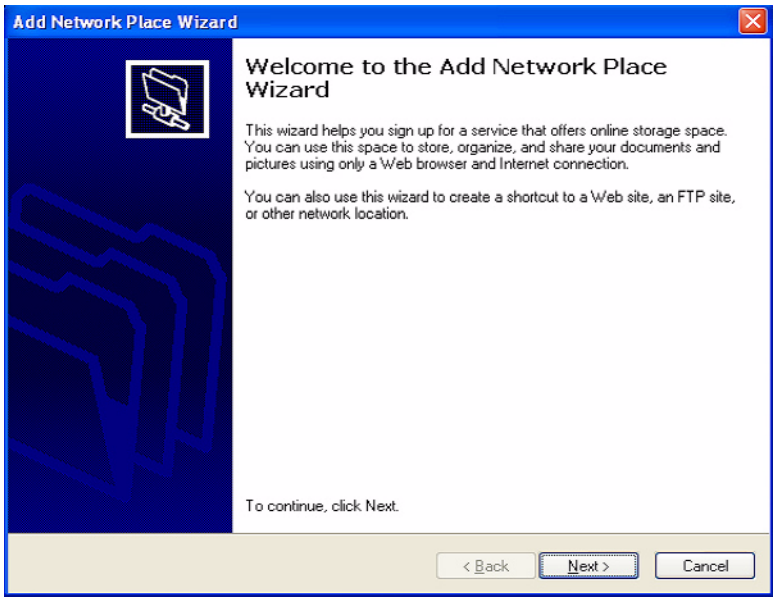

Add Network Place Wizard
Welcome to the Add Network Place Wizard
This wizard helps you sign up for a service that offers online storage space. You can use this space to store, organize, and share your documents and pictures using only a Web browser and Internet connection.
You can also use this wizard to create a shortcut to a Web site, an FTP site, or other network location.
To continue, click Next.
< Back
Next >
Cancel

Figure 56 Add Network Place Wizard welcome dialog

4. Click **Next**. The wizard will ask you, **Where do you want to create this network place?**

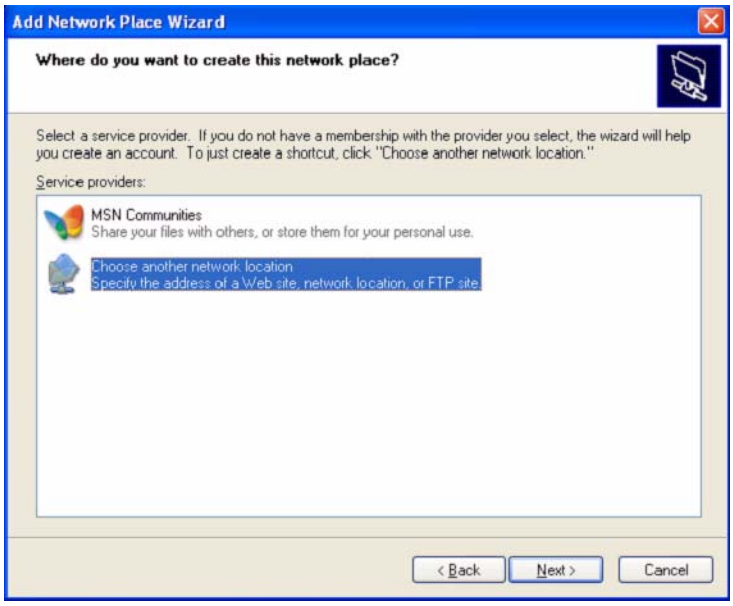

Add Network Place Wizard
Where do you want to create this network place?
Select a service provider. If you do not have a membership with the provider you select, the wizard will help you create an account. To just create a shortcut, click "Choose another network location."
Service providers:
MSN Communities
Share your files with others, or store them for your personal use.
Choose another network location
Specify the address of a Web site, network location, or FTP site.
< Back
Next >
Cancel

Figure 57 Choose where to create the new network place

5. Select **Choose another network location** and click **Next**. The wizard will ask you, **What is the address of this network place?**

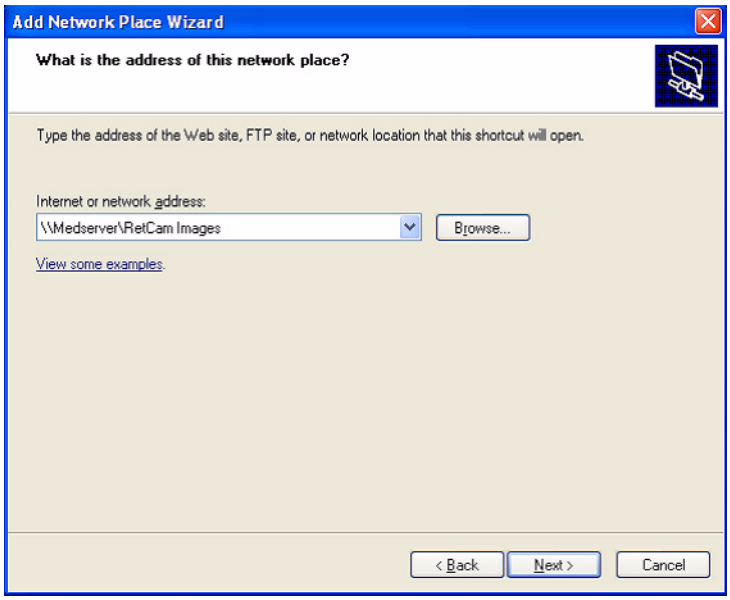

Add Network Place Wizard
What is the address of this network place?
Type the address of the Web site, FTP site, or network location that this shortcut will open.
Internet or network address:
\\Medserver\RetCam Images
Browse...
View some examples.
< Back
Next >
Cancel

Figure 58 Specify the address of the new network place

6. Type in the path of the new network file share to be accessed, for example, enter **\\MedServer\RetCam Images**, including the backslashes as shown. Then click **Next**.

☞ **Note: You can also map to a subfolder of the file share, for example, \\MedServer\RetCam Images\RetCam.**

Now the system will prompt you to enter the username and password with which you will logon to access the network file share on the target system (the server).

Figure 59 Connect to target system

7. In the indicated fields, enter a valid user name prefaced by the domain name and a backslash with no spaces, and the corresponding password for the target system.

☞ **Note: The user name [UserID] in the example, must be prefaced by the domain name and backslash, in the format [DomainName]\[UserID], as shown.**

8. Be sure to select the **Remember my password** checkbox to ensure the target drive will be accessible automatically for future access. Then click **OK**. The wizard will now ask you, **What do you want to name this network place?**

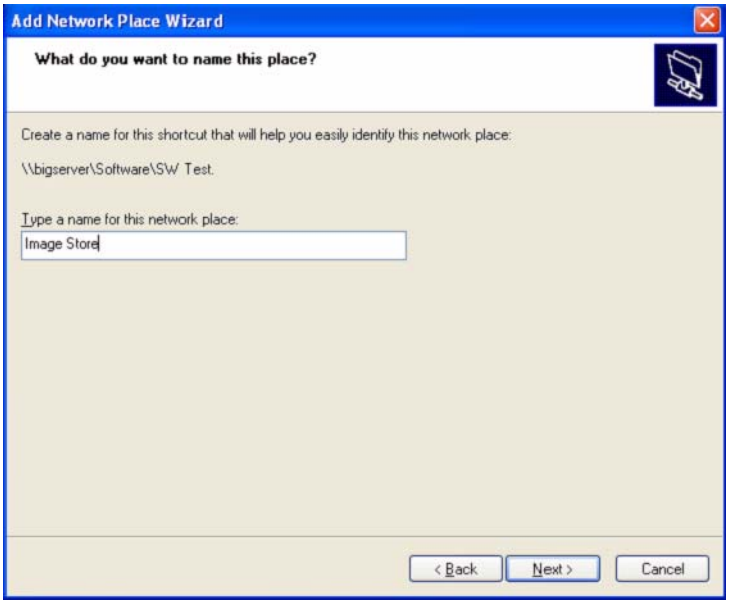

Add Network Place Wizard
What do you want to name this place?
Create a name for this shortcut that will help you easily identify this network place:
\\bigserver\Software\SW Test
Type a name for this network place:
Image Store
< Back
Next >
Cancel

Figure 60 Type a name for the new network place

9. Type in the name to be used for the new network file share from the RetCam, for example, **Image Store**, as shown. Then click **Next**. The Wizard Complete dialog appears.

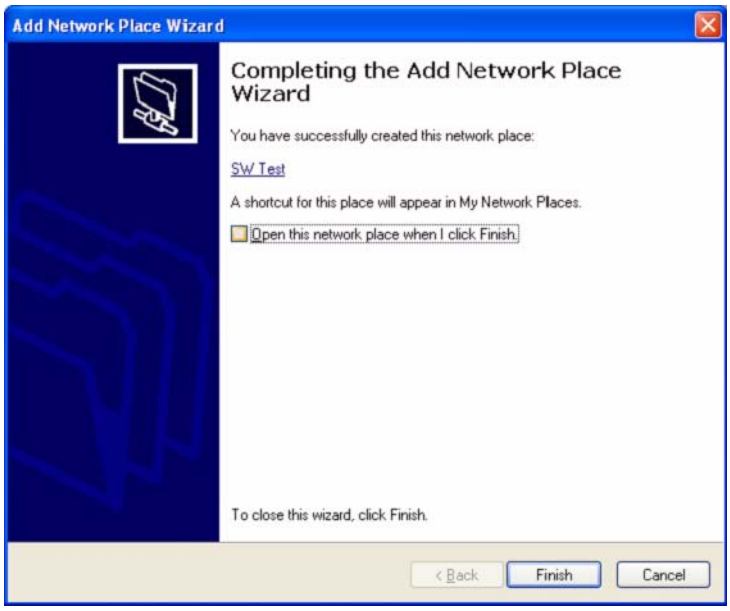

Add Network Place Wizard
Completing the Add Network Place Wizard
You have successfully created this network place:
SW Test
A shortcut for this place will appear in My Network Places.
Open this network place when I click Finish.
To close this wizard, click Finish.
< Back
Finish
Cancel

Figure 61 Completing the Add Network Place Wizard

10. Clear the **Open this network place when I click Finish** checkbox. Then click **Finish**. You will return to the Network Connections dialog.
11. Close the Network Connections dialog.

Accessing the Network Place

When using the RetCam import or export features from the Transfer screen, the network place you added will be visible in the Browse for Folder dialog as in the example below.

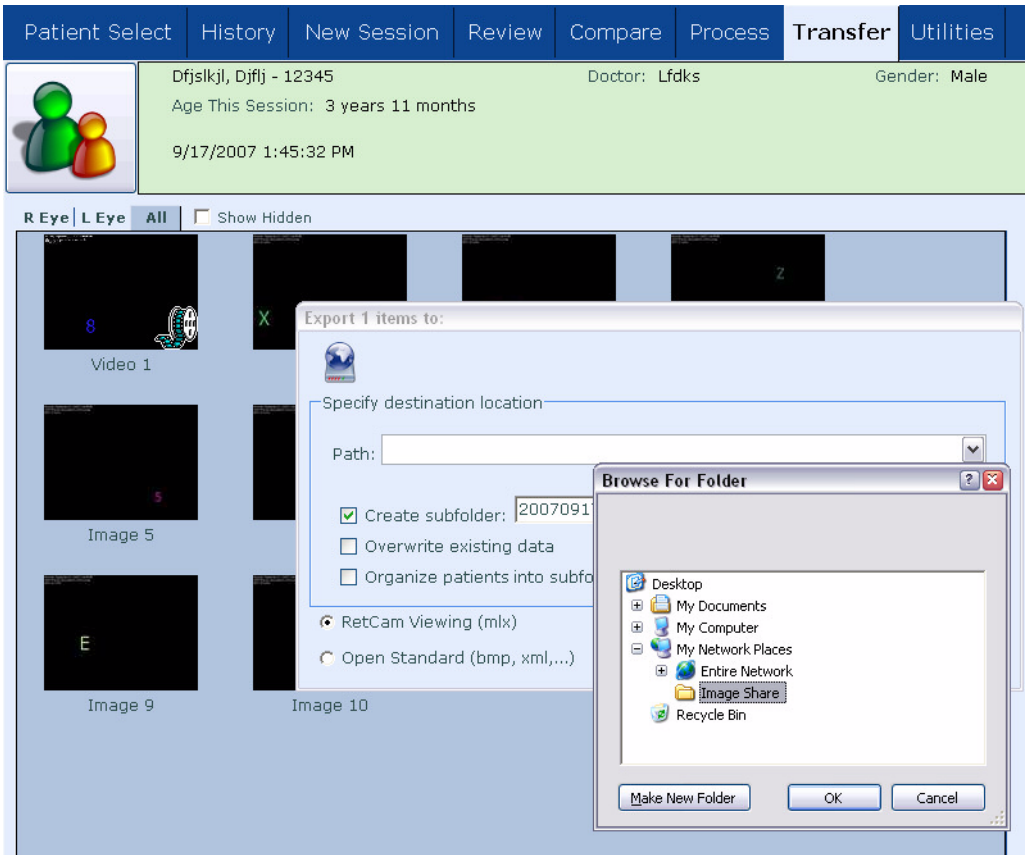


Figure 62 Accessing the network place created

All subfolders of the network place can then be accessed as permitted by the privileges associated with the user name used to create the network file share.

Removing a Network Place

There is no limit to the number of network places which can be added. Should you want to remove a network place to eliminate access for a given user account, follow these steps.

1. Click the **Connections** button in the Utilities Screen (see page 95) to open the Network Connections dialog.

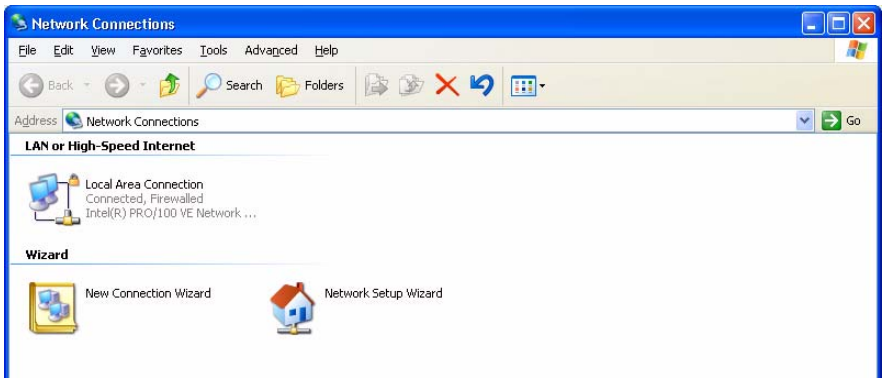
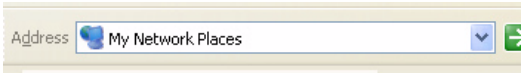


Figure 63 Network Connections dialog

2. In the address bar, type in **My Network Places** and press **Enter**.



3. In the list that appears, select the network place you wish to remove and press the **Delete** key. A dialog will prompt you to confirm deletion.
4. Select **Yes** to confirm deletion.
5. Close the My Network Places dialog.

Connecting RetCam Devices to an Existing Network

RetCam II and RetCam Shuttle are shipped with Dynamic Host Configuration Protocol (DHCP) active, to automatically obtain the computer's IP address for TCP/IP communications. This will work for most networks. If, however, the network does not contain a DHCP server (usually on smaller networks), a static IP address must be specified. The network administrator must specify the appropriate IP address, subnet mask and default gateway server addresses. Once these are determined, follow the steps below to apply them:

1. Click the **Connections** button in the Utilities Screen (see page 95) to open the Network Connections dialog.

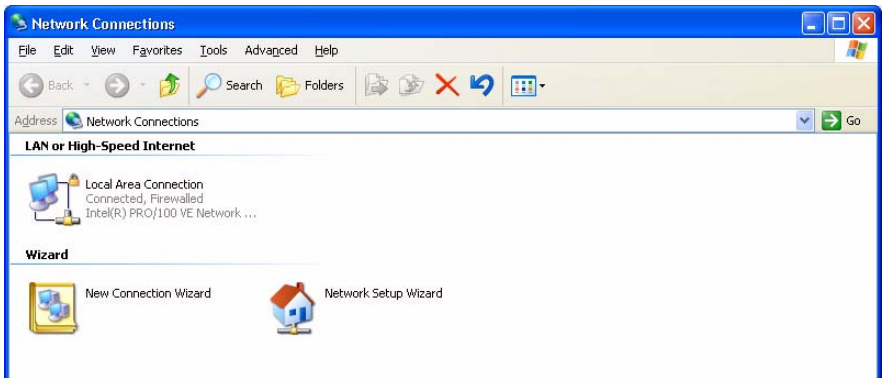


Figure 64 Network Connections dialog

2. Right-click **Local Area Connection** and select **Properties**. The Local Area Connection Properties dialog appears.

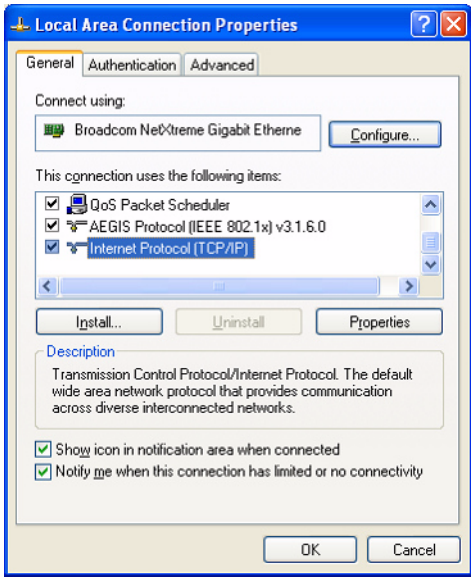


Figure 65 Local Area Connection Properties dialog

3. Click on **Internet Protocol (TCP/IP)** and select **Properties**. The Internet Protocol (TCP/IP) Properties dialog appears.

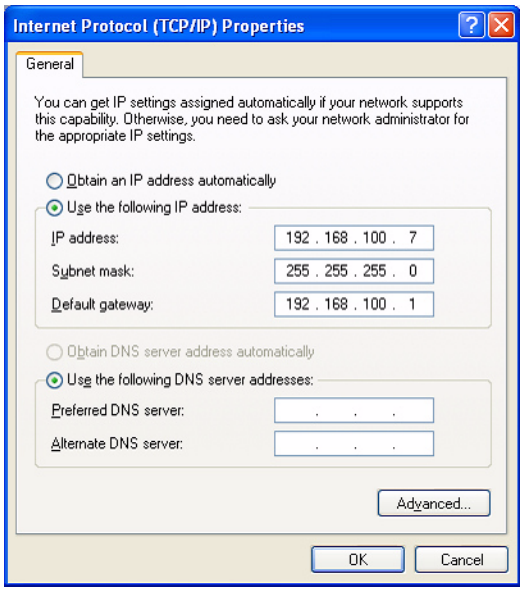

Internet Protocol (TCP/IP) Properties
General
You can get IP settings assigned automatically if your network supports this capability. Otherwise, you need to ask your network administrator for the appropriate IP settings.
Obtain an IP address automatically
Use the following IP address:
IP address:
192 . 168 . 100 . 7
Subnet mask:
255 . 255 . 255 . 0
Default gateway:
192 . 168 . 100 . 1
Obtain DNS server address automatically
Use the following DNS server addresses:
Preferred DNS server:
Alternate DNS server:
Advanced...
OK
Cancel

Figure 66 Internet Protocol (TCP/IP) Properties dialog

4. Select the **Use the following IP address:** radio button.
5. In the indicated fields, enter the assigned **IP Address**, **Subnet mask** and **Default gateway**. (The addresses shown above are for example only. The actual addresses must be specified by your network administrator.) Then click **OK**. Local Area Connection Properties dialog reappears.
6. Click **OK** again in the Local Area Connection Properties dialog. Network Connections dialog reappears.
7. Close the Networking Connections dialog.
8. If prompted, allow the system to restart for your changes to take effect.

7 Utilities

The section describes the utilities available in the Utilities screen, including:

- System Identification, page 95
- Version Information, page 96
- Networking Connections, page 96
- Adjust Date/Time, page 96
- Adjust Volume, page 96
- Printers, page 96
- Disk Management, page 97

Utilities Screen

The Utilities screen appears when you select its tab or press F8 on the keyboard.

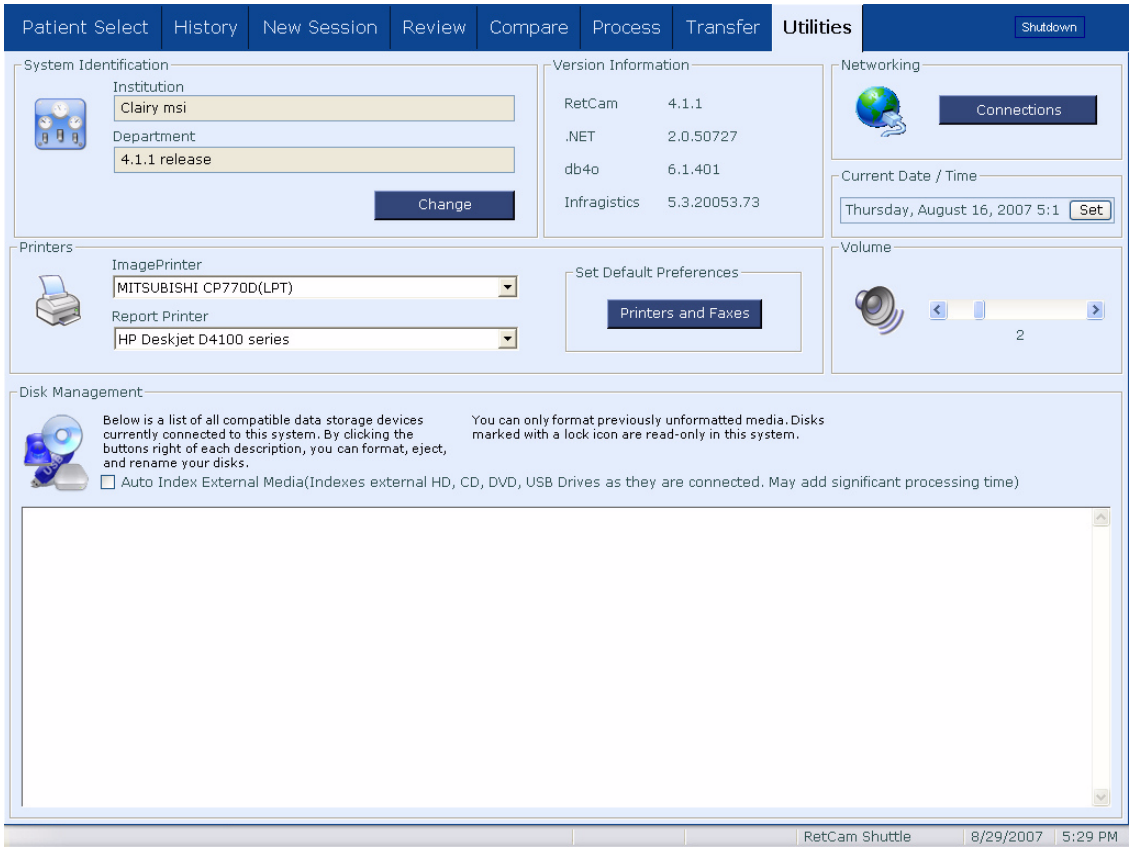


Figure 67 Utilities screen

System Identification

In the System Identification area, click **Change** to edit the Institution and/or Department fields. This will not change the combination institution-department

name used to identify the site in the Site Awareness dialog (see Establish Site Awareness on page 28), which you can only change through that dialog.

Version Information

The Version Information area at upper center displays the current version information, the details of which may be useful when communicating with Clarity Customer Service about your system.

Networking Connections

Click the **Connections** button in the Networking area on the right side as a shortcut to open the Windows Network Connections dialog, where you can configure the Shuttle notebook for network access. For details, see Networking a RetCam Shuttle on page 85.

WARNING: There is no automatic backup of data on the FIFO buffer, which means that permanent loss of data is possible if no backup solution is employed. See Chapter 6 Data Transfer for instructions to implement backup.

Adjust Date/Time

In the Current Date / Time area, click **Set** to adjust the system date and time.

☞ **Note: When you change the time zone, you must reboot the system for the time zone change to take effect.**

Adjust Volume

In the Volume area at right, click the arrows or click above or below the slider or drag the slider to adjust the speaker volume.

Printers

In the Printers area at left, use the drop-lists in the Image Printer and Report Printer fields to select the printer to be used for each application.

☞ **Note: Clarity recommends that you use only those printers that Clarity supplies or has identified for use with the RetCam Shuttle.**

Printers and Faxes

Click **Printers and Faxes** (in the Set Default Preferences area) to open the Printers and Faxes dialog, where you can add a new printer or set default printing preferences for printers attached to the system.

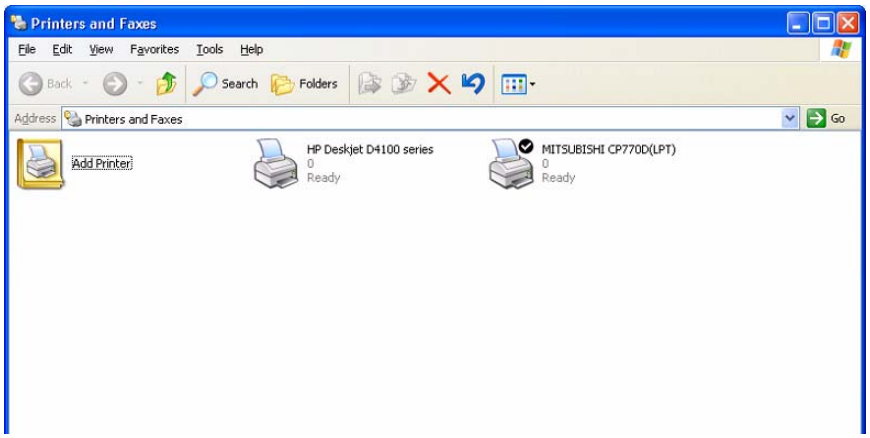


Figure 68 Printers and Faxes dialog

Disk Management

In the Disk Management area at lower center, the list displays all drives for removable media currently installed in the system. Click to highlight the drive, then click the desired function.

Auto Index External Media Checkbox

This checkbox is unselected by default. When you select it, it turns on automatic indexing of external media when you connect to them. This means that, when the **Other Media** option is selected on the Patient Select screen, you must wait for indexing to occur before patients appear in the patient list. (See Select Data Source on page 40.)

☞ **Note: When you select or deselect this checkbox, you must reboot the system for the change to take effect.**

Eject

Click the **Eject** button next to the desired drive to safely remove the installed media.

8 Maintenance and Support

This section addresses maintenance and support under the following topics:

- Recommended Maintenance Schedule, below
- Cleaning Procedures, below
- Fuse Replacement, page 109
- Replace Illumination Lamp, page 110
- Key Validation, page 112
- Technical Support, page 114
- Service Information, page 115

Recommended Maintenance Schedule

Between patients: Clean and inspect lens piece.

Weekly: Wipe down the system.

Monthly: Inspect cables and connections for wear.

Burned out bulb: Replace illumination bulb

Blown fuse: Replace system fuses

Cleaning Procedures

For cleaning purposes, the RetCam Shuttle is divided into two categories:

- The Lens Piece that contacts the patient
- The rest of the system

Cleaning the Lens Piece

The Lens Piece should be cleaned thoroughly between patients to prevent the spread of infectious disease. As recommended by the American Academy of Ophthalmology, the cleaning liquid of choice is 70% isopropyl alcohol. Moisten a clean towelette with the solution and use a gentle wiping action across the front of the lens piece, being sure to pay special attention to the concave contact lens area. To prevent irritation to the next patient from residue left on the lens, rinse the tip of the lens piece thoroughly with disinfected distilled water.

WARNING: To avoid damage, do not autoclave any part of the RetCam system.

The American Academy of Ophthalmology also recommends disinfecting with 1:10 dilution of bleach for 5 minutes. (Refer to the AAO page inserts starting on page 101.)

WARNING: To handle chemicals safely, consult Material Safety Data Sheets (MSDS) before using isopropyl alcohol or bleach.

Note: If you disinfect with bleach, you must rinse the frontmost part of the lens piece with disinfected distilled water, and make sure the lens piece is wiped completely clean before using on a patient.

Note: Never immerse the entire lens piece or handpiece in any liquid or solution. For disinfection purposes, you can immerse no more than 4 mm (about 1/6") of the tip of the lens piece, in an inverted position, FOR NO MORE THAN 15 MINUTES. Immersing more or longer than this causes corrosion of the lens piece and voids the lens warranty. Use water, bleach, 3% hydrogen peroxide or isopropyl alcohol. Permissible immersion depth is illustrated in Figure 69 below. It is important not to immerse the joint where the polished metal tip meets the painted housing, since it is susceptible to corrosion.

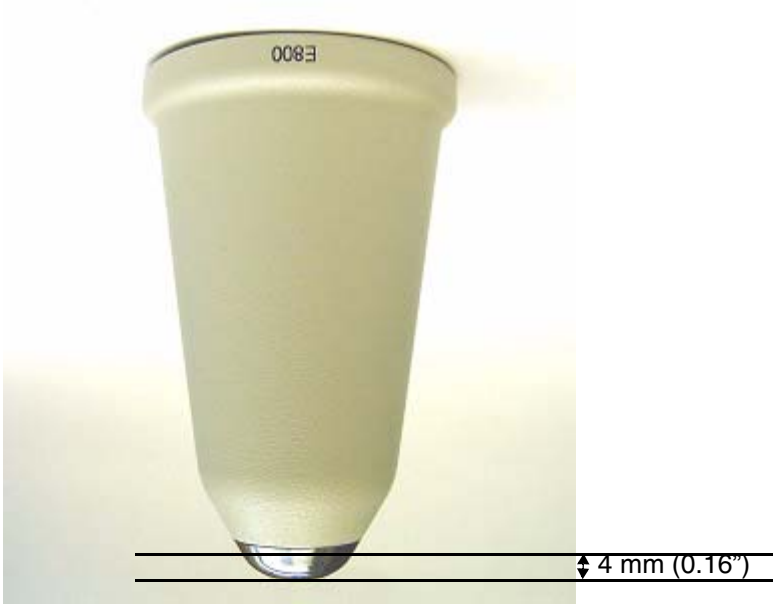


Figure 69 Inverted lens piece showing permissible depth of immersion

Cleaning the Rest of the System

As with any medical device, use good public health practices when handling the equipment, based on CDC guidelines. In addition, as with typical office equipment, a gentle wiping with a cloth moistened with mild soap and/or water is recommended. Do not spray cleaning solutions directly on the computer or other modules, spray the cloth instead. The cart and side panels also cannot be sprayed, but only the cloth with which you wipe, to avoid introducing spray or mist inside the system. Use only a mild soap and/or water solution.

The lens piece should be checked before each use for damage to the front contact lens and surrounding surface. The interconnect cable and connectors should be checked for damage to the end connectors and protective covers.

WARNING: Always inspect the lens before use for damage such as chips, cracks or roughness that could injure the patient's eye.

Information Statement

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

Minimizing Transmission of Bloodborne Pathogens and Surface Infectious Agents in Ophthalmic Offices and Operating Rooms

Introduction

This document is intended to provide guidance to ophthalmologists and their staff about minimizing transmission of infection in their offices and operating rooms. This document addresses prevention of bloodborne pathogens such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV), and other viruses, such as adenovirus and herpes simplex virus. These recommendations are mainly based on broad guidelines issued by the U.S. Department of Health and Human Services (DHHS) and the U.S. Department of Labor for health care workers.

Bloodborne pathogens may be present in blood, blood-contaminated products or other bodily fluids especially if contaminated with or mixed with blood. Percutaneous injuries (e.g., a needlestick or cut with a sharp object) represent the greatest risk of transmission of bloodborne pathogens to health care workers. Universal precautions apply to blood and other body fluids containing visible blood, but not to tears unless they contain visible blood.[1] The use of universal precautions, including handwashing and barriers, reduces contact with blood and bodily fluids, thus reducing exposure of health care workers to bloodborne pathogens. The use of safety devices and techniques to reduce handling of sharp instruments also reduces the number of percutaneous injuries.

Exposure to HIV in health care settings has been of major concern. As of June, 2000, the Centers for Disease Control and Prevention (CDC) received reports of 56 U.S. health care personnel with HIV transmission associated with occupational exposure, and another 138 reports of possible transmission to date.[2] For health care personnel exposed through percutaneous means to HIV-infected blood, the estimated risk for HIV infection is 0.3%.[2] Risks associated with a mucous membrane exposure are estimated to be 0.09%.[2] Risks for HIV seroconversion after a percutaneous exposure have been found higher for those exposed to a larger quantity of blood, (i.e., a device visibly contaminated with blood, a needle being placed directly in a vein or artery, or a deep injury) or when the source patient was terminally ill with AIDS.[2]

Transmission of HBV poses a risk to health care workers. In 1994, approximately 1,000 health care workers were infected with HBV from occupational exposure.[2] Since implementation of routine preexposure vaccination of health care personnel and precautions to prevent exposure to blood, there has been a significant decrease in HBV infection among health care personnel.[2] HBV is transmitted by mucosal or percutaneous exposure to blood and serum-derived body fluids from persons with acute or chronic infection. The risk of developing clinical hepatitis from exposure to the blood that was both hepatitis B surface antigen (HbsAg) and hepatitis E antigen (HbeAg) positive was 22 to 31%.[2] Any person who is seropositive for hepatitis B surface antigen can be infectious. The CDC recommends that health care personnel who have routine contact with blood and bodily fluids be vaccinated.[3] For applicable settings, the OSHA standard requires that hepatitis B vaccine be made available to personnel with occupational exposure to blood, at the employer's expense.[4]

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HCV is the cause of most parenterally transmitted cases of non-A, non-B hepatitis in the U.S. There is no vaccine currently available and postexposure prophylaxis has not appeared effective in preventing infection. HCV is thought to be transmitted relatively rarely through occupational exposure to blood.[2] The incidence of seroconversion after percutaneous exposure to an HCV-positive source is estimated to be 1.8%.[2] Hepatitis C virus (HCV) has been isolated in tears and aqueous humor.

Adenovirus has been the main cause of nosocomial outbreaks of conjunctivitis. These outbreaks have mostly occurred in eye clinics or offices. Adenovirus can survive for long periods on environmental surfaces and ophthalmic instruments can become contaminated and transmit infection. Handwashing, glove use and disinfection of instruments can all help to prevent or limit the transmission of adenovirus. Infected personnel should not provide patient care for the duration of symptoms after onset of adenoviral conjunctivitis

Background

The National Society to Prevent Blindness, in cooperation with the American Academy of Ophthalmology assembled a Task Force to examine the risk of acquiring HIV infection in the course of eye examinations and treatments. The Task Force helped develop precautions to reduce spread of pathogens that might be present in tears.[5]

In August 1987, the Centers for Disease Control and Prevention (CDC) issued revised recommendations for the prevention of HIV transmission in a health-care setting.[6] This was followed two months later by a joint advisory notice from the U.S. Department of Labor and the U.S. Department of Health and Human Services regarding the protection against occupational exposure to HBV and HIV.[7] These documents addressed the risk that health care workers may face in the course of their duties and made broad recommendations labelled universal precautions that all health care workers should follow. Neither document distinguished the risks and needs of healthcare workers in ophthalmology from any other health care occupation.

In June 1988, the CDC further clarified their recommendations, particularly as they relate to the protection of health care workers, by stressing the far greater risk of bloodborne viral infections (e.g., HIV and HBV) posed by blood and blood-contaminated bodily fluids than by such bodily secretions as tears.[8] In that document, they noted that "Universal precautions do not apply to ... nasal secretions, sputum, sweat, tears... unless they contain visible blood." Thus, normal tear exposure does not require bloodborne pathogen precautions. In June, 2001, the U.S. Public Health Services updated recommendations for the management of occupational exposures to HBV, HCV and HIV.[2]

In March 1992, the Occupational Safety and Health Administration (OSHA), issued a set of regulations entitled, "Occupational Exposure to Bloodborne Pathogens, "which requires that employers establish safeguards which protect workers against hazards related to bloodborne pathogens.[4] These regulations require identification of who is at risk of occupational exposure, the communication of hazards to employees at risk for exposure, exposure prevention control measures, and what to do if an exposure occurs. In April 2001, the Needlestick Safety and Prevention Act became effective, revising the bloodborne pathogens standard to require employers identify and make use of safer medical devices which can be used to reduce worker exposure.[9]

In 1992, the American Academy of Ophthalmology Public Health Committee developed updated recommendations for ophthalmic practice in relation to HIV.[10] The Committee noted that there were two distinct areas of concern to ophthalmic medical personnel and patients:

1. Transmission of ocular surface infectious agents such as adenovirus or herpes virus. Prevention of transmission of these pathogens requires good hygienic techniques, such as routine hand washing, tonometry cleaning and trial contact lens disinfection.

2. Transmission of bloodborne pathogens such as HIV or HBV. Prevention of transmission of these agents requires the use of bloodborne pathogen precautions, which include the proper use of gloves, needle disposal and other precautions such as administering hepatitis B vaccine in workers exposed to bloodborne pathogens.

Recommendations

The Committee recommended specific measures that would provide adequate protection for the patient, for health care workers in the ophthalmic care setting, and for the ophthalmologist. This document updates four areas:

- Procedures for protection of the patient
- Procedures for protection of the staff
- Procedures for protection of the ophthalmologist
- Responsibilities toward patients with known or suspected HIV infection

I. Procedures for Protection of the Patient

Protection of patients from exposure to the HIV during examination and treatment of eye disorders incorporates

the application of good public health principles and specialized precautions. Since the infection was first recognized in 1981, there has been no evidence to indicate that the HIV has been transmitted through any of the diagnostic or surgical procedures performed by ophthalmologists. According to the CDC, the likelihood of transmission through contact with tears is extremely remote.[8] However, because the virus is potentially lethal, is present in surface epithelia in the eye and in low titers in tears and ocular fluids of infected individuals, and can (in theory at least) be transmitted through mucous membranes, public health officials have recommended that reasonable precautions be taken. Furthermore, because many HIV carriers may be unaware of their infection and show no sign of the disease, the following recommendations should be routinely used for **all** patients. Recommendations for the safe usage of ophthalmic instruments and contact lenses are provided. These guidelines represent good, general ophthalmic technique, because they reduce the risk of transmitting both bloodborne pathogens (HIV, HBV and HCV) and surface infectious agents (e.g., herpes simplex virus, adenovirus, etc.) likely to be encountered in patients presenting for eye examinations.

Recommendations

A. Handwashing.

Handwashing represents the single most effective means of avoiding the risk of transmitting or acquiring infections in the course of examination.[11] The CDC recommends that ophthalmic medical personnel performing eye examinations or other procedures involving contact with tears should wash their hands immediately after a procedure and between patients.[5] Handwashing should be encouraged when there is any doubt about the necessity for doing so. For routine handwashing, a vigorous rubbing together of all surfaces of the lathered hands is recommended for at least 10 seconds, followed by a thorough rinsing under a stream of water.[11] Plain soap can be used for handwashing for most routine activities. Gloves may be used as an extra margin of safety. When gloves are worn, handwashing is still recommended because gloves can become perforated and bacteria can grow rapidly on gloved hands. If there are cuts, scratches, or dermatological lesions (e.g., weeping lesions) on the hands, then use of gloves is advisable.

B. Eyedrops.

The bottle tip should not come into direct contact with the patient's tears or conjunctiva. If the tip does touch the patient, the bottle should be discarded.

C. Gowns, masks and protective eye wear.

Gowns, masks and protective eyewear are unnecessary for the usual ophthalmic examination.

D. Disinfection procedures.

Disinfection is a process to eliminate most or all pathogenic microorganisms from inanimate objects, such as medical devices or equipment.[12] This is usually performed using chemicals known as germicides or disinfectants. High-level disinfection kills all organisms and is performed suing a germicide which is regulated by the Food and Drug Administration. The CDC recommends that if there are questions about high-level disinfectants or how to disinfect a particular medical device, the office should contact the manufacturer of the product.[13]

The CDC has recommended the following, which are proven to inactivate infectious HIV, herpes simplex virus, and adenovirus.[5]

- Wiping clean and then disinfecting with bleach is recommended by the CDC as an effective way to inactivate HIV. Remove the entire prism from the tonometer and place it in a suitable receptacle that allows the applanating surface and adjacent 2–3 mm of the tonometer to be immersed in a 1:10 dilution of household bleach (sodium hypochlorite). One method uses a Petri dish with small holes drilled in the lid, which allows just the tonometer tip to be partially immersed in the solution.[14] After a five-minute period of soaking, the tip should be washed under running water and dried before use. Two tonometer prisms should be available so that one can be used while the other is being disinfected. Soaking the entire tip may eventually remove the coloring of the etched calibration marks. These disinfecting solutions should be changed at least once daily.

- As an alternative, the CDC recommends that a similar approach with a 5 to 10 minute exposure to a fresh solution of either 3% hydrogen peroxide, 70% ethanol, or 70% isopropanol can be followed. These solutions need to be changed at least twice daily.

Goldmann-type Tonometers

A recent study compared several methods of disinfecting Goldmann tonometer tips, which were inoculated with hepatitis C virus.[15] The methods that resulted in the greatest decrease in concentration of HCV RNA were a 5-minute soak in 3% hydrogen peroxide or 70% isopropyl

alcohol following by washing in cold water. A 5-second 70% isopropyl alcohol wipe was not as effective, and a 5-second wipe with povidone iodine was more effective than the isopropyl alcohol wipe in reducing HCV RNA.

The washes are important to avoid corneal de-epithelialization that might be caused by residual disinfectant solution.

Schiotz Tonometer

The tonometer should be dissembled between each use, cleaning the barrel with two pipe cleaners (the first soaked in alcohol, the second dry) and the footplate with an alcohol swab. All surfaces must be dried before reassembly. Disposable covers are also available.

Non-contact Tonometers

The non-contact tonometer may not make contact with the cornea or tears, but may cause micro-aerosol formation. The front surface may be wiped with an alcohol-soaked sponge since it may occasionally touch the eye.

Digital Pneumotonometer

Tips of pneumotonometers should be cleaned with an alcohol sponge, taking care that the surface is dry before using it again. It is important to allow the alcohol to evaporate completely to avoid damage to the corneal epithelium.

Diagnostic Contact Lenses (Goldmann, etc.)

The lens is inverted so that the contact lens surface is uppermost. The outer casing and inner surface of the lens are then vigorously wiped with an alcohol sponge
As an alternative, the inner cup may be filled to the rim or partly immersed within a fresh 1:10 dilution of household bleach. After five minutes, the bleach is removed and the device is briskly irrigated with running water and dried. This method allows cleansing of the outer surface of the lens as well as the contact portion without exposing the anti-reflective coating on the operator surface of the contact lens to the bleach. It is important to rinse to avoid corneal de-epithelialization that might be caused by residual disinfectant solution.

Other Instruments That May Come Into Contact With Patients

The HIV is a fragile virus and there is no evidence of casual spread from surfaces of ophthalmic instruments. However, it is known that other viruses, such as adenovirus, may persist for many hours on a dry surface and, thus, could conceivably be transmitted to other patients.[16] Therefore, if an instrument, such as a slit lamp biomicroscope, has been used for a patient who is suspected of having an ocular infectious disease, it is strongly recommended that the surfaces on the instrument be cleaned with alcohol or bleach.

Trial Fitting Contact Lenses

Contact lenses need to be disinfected between patients. Rigid gas permeable and hard contact lenses can be disinfected using a hydrogen peroxide or a chlorhexidene-containing disinfectant system. Soft contact lenses can be disinfected with either hydrogen peroxide or a heat disinfection system.[5]

E. Tissue Transplantation.

The Eye Bank Association of America has strict criteria in place to screen corneal and scleral tissue for transplantation, to prevent transmission of diseases. There have been no confirmed cases of occupational transmission of transmissible spongiform encephalopathies, such as Creutzfeld-Jakob disease. The CDC recommends use of stringent chemical and autoclave sterilization methods for heat-resistant instruments that come into contact with high infectivity tissues in patients with suspected or confirmed CJD.[17] For infection control of transmissible spongiform encephalopathies, the World Health Organization recommends the following in situations where there is contact with high infectivity tissues in patients with suspected or confirmed CJD:[18]

1. Use single-use surgical instruments
2. Avoid mixing instruments used on tissues of high infectivity vs. no infectivity
3. Destroy re-usable instruments, where possible
4. If destruction is not possible, decontaminate instruments.

The Risk of Acquiring HIV Infection from Ophthalmic Medical Personnel

The risk of patients being infected by an ophthalmologist or ophthalmic medical personnel who has been infected with the HIV is considered extremely remote. Standard office practices, as discussed above, will minimize even the unlikely risk of contamination of patients. Surgical patients are protected by the routine use of barriers (e.g., gloves). Certainly, an instrument that punctures the skin of an ophthalmologist or the surgical assistant must be removed from the operating field and sterilized. The surgeon or assistant must reglove after all bleeding has stopped and any residual blood has been removed.

The CDC Guideline for Infection Control in Healthcare Personnel also provides advice about management of patient contact and other situations when health care personnel have HIV and other illnesses which could be transmitted to patients.[19]

II. Procedures for Protection for the Staff

Protection of the ophthalmic medical personnel involves preventive measures to avoid infection with ocular surface contaminants (such as adenovirus or herpes simplex virus), as well as bloodborne pathogens (such as HIV, HBV and HCV).

Bloodborne pathogen precautions further reduce the unlikely risk of contamination of the ophthalmic medical personnel and patient, alike. Employers under OSHA's rule with health care workers who are exposed to bloodborne pathogens are required to establish a program that informs employees and employers of the risks of occupational exposure to bloodborne pathogens and how to reduce those risks.[3]

Human tears are not considered to contain significant amounts of bloodborne pathogens, and thus do not require OSHA's bloodborne pathogen precautions; but exposure to human tears does require good office hygiene practices such as handwashing. However, contact with tears contaminated with blood, such as in minor surgery, requires the use of bloodborne pathogen precautions.

As the prevalence of HIV infection continues to increase throughout the United States, it is inevitable that patients carrying HIV will be more commonly encountered in eye examining rooms and in surgery. Some of these patients will be known to be infected with the HIV, but in many, it will be unrecognized. All health care personnel engaged in delivering ophthalmic care to such patients might, in the course of their normal duties, be exposed to the blood of individuals who may be shedding the virus. Although the risk of infection in these circumstances appears to be extremely remote, precautions by health care employers and employees are justified as recommended by the OSHA and the CDC.

The following recommendations for hygienic procedures to be used in the delivery of eye care to patients are effective ways to minimize this risk as well as the risks of contracting or transmitting other much more common infectious diseases encountered in patients. Because it is impractical to identify all patients who may be carrying these infectious agents, these recommendations should be the routine for all patient encounters.

General Precautions Against Infection – Office

A. Handwashing.

The hands should be washed with soap and water and thoroughly dried on a fresh or disposable towel between each eye examination. Fingernails should be kept short and clean. The hands and fingers should be inspected frequently for cuts, abrasions, and breaks in the skin or paronychia.

B. Gloves.

The CDC suggests in its recommendations for the prevention of HIV transmission in health care setting, released in 1987[7], and updated in 1988[8], that:

> "All health care workers should routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with the blood or blood-contaminated fluids of any patient is anticipated. Gloves should be worn for touching blood and blood-contaminated fluids, for handling items or surfaces soiled with such fluids and for performing venipuncture and other vascular access procedures. Gloves should be changed after contact with each patient. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other bodily fluids. Hands should be washed immediately after gloves are removed.
>
> Health care workers who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment until the condition resolves.
>
> Pregnant health care workers are not known to be a greater risk of contracting HIV infection than health care workers who are not pregnant; however, if a health care worker develops HIV infection during pregnancy, the infant is at risk of infection resulting from perinatal transmission. Because of this risk, pregnant health care workers should be especially familiar with and strictly adhere to precautions to minimize the risk of HIV transmission."

In accordance with these recommendations, disposable gloves should be readily available for all ophthalmic medical personnel and they should be instructed regarding the rationale for wearing gloves and their appropriate usage. It should be noted particularly that gloves:

- Are not a substitute for handwashing, and
- Are for single use only, and should be discarded after each patient encounter.

C. Gowns and Masks.

Gowns and masks are unnecessary in the normal ophthalmic office setting.

D. Protective eye wear.

In situations when splashing with blood or blood-contaminated fluids may be anticipated, protective eyewear is indicated.

E. Handling of tissue.

In the course of assisting in the examination of eye patients, ophthalmic medical personnel may be required to handle the eyelids and surrounding facial skin and thus, may come in contact with tears and the conjunctival membrane. To minimize direct contact with these tissues, particularly if the patient has a known or suspected eye infection, ophthalmic medical personnel should be instructed in the use of gloves or in "no-touch" techniques involving the use of cotton-tipped applicators to stabilize the tissues whenever possible.

F. Hepatitis B vaccination.

Ophthalmic medical personnel who frequently come in contact with needles, blood or blood products are advised to receive hepatitis B vaccine to avoid infection with the virus.[3] OSHA regulations require that the employer make hepatitis B vaccine available to all employees who have occupational exposure.[4]

Procedures

A. Handling of sharp instruments.

The CDC has recommended that all health care workers adopt precautions to prevent injuries caused by needles, scalpels and other sharp instruments or devices[8]:

- During procedures
- When cleaning used instruments
- When disposing of used needles, and
- When handling sharp instruments after procedures

To prevent needlestick injuries, ophthalmic medical personnel should be instructed in the proper handling of needles, i.e., needles should not be recapped, or purposely bent or broken by hand, removed from disposable syringes or otherwise manipulated by hand. Health care workers should be instructed to place disposable syringes and needles, scalpel blades and other sharp items in puncture resistant containers following their use. Puncture resistant containers should be provided and should be located as close as practical to the area where needles and syringes are in use. Newer devices have engineering controls such as injury protections and needleless systems to minimize injuries.

OSHA's revised Occupational Exposure to Bloodborne Pathogens Standard now requires that the employers governed by this rule review annually and update to reflect changes in technology that could reduce exposure to bloodborne pathogens, and maintain a sharps injury log.[20] OSHA's Bloodborne Pathogens Standards applies to all employers with employees who have occupational exposure to blood or other potentially infectious materials. However, workplaces with 10 or fewer employers are exempt from OSHA recordkeeping requirements, including a Sharps Injury Log.[21]

B. Fluorescein and Indocyanine green (ICG) angiography.

It is recommended that photographers and other health care workers who may come in contact with blood while performing fluorescein and ICG angiography wear gloves and adhere to the procedures as outlined in this section.

C. Contact lens fitting.

Ophthalmic medical personnel involved in the fitting of contact lenses should be instructed in the precautions outlined by the CDC for disinfection of lenses.[4]

D. Minor office surgical and diagnostic procedures.

During the performance of minor surgical and diagnostic procedures, particularly where contact with blood or blood-contaminated fluids may occur, gowns, disposable gloves and masks, and protective eyewear should be worn.

Surgery

Ophthalmic medical personnel assisting at eye surgery should be instructed to avoid the direct handling of needles and those parts of instruments that have come into contact with body tissues and fluids. Thus, needles should be manipulated with forceps or needle holders rather than by the gloved fingers, instruments should be held by the handle rather than by the tips, and the cleaning of instruments should be performed in such a way that accidental perforation of the gloves is avoided. If an instrument punctures a glove or the skin, it must be removed from the operating field and sterilized. These practices should be incorporated into standard operating room infection control procedures and should be monitored for compliance, as are other infection control procedures.

If an ophthalmic medical personnel does accidentally sustain a skin puncture, the following actions should be taken. The individual should temporarily discontinue participation in surgery (if possible) and cleanse the wound for five minutes with an antiseptic solution.

The wound should then be dressed with a bandage after rescrubbing. If there is no oozing or weeping of the wound, the person may reglove, and complete the surgery.

Under experimental conditions, it has been reported that oral polio vaccine virus was cultured from the laser plume after excimer laser ablation.[22] Another experimental study postulated that infectious virus particles could be aerosolized during excimer laser photoablation.[23] Another study using a model system did not find any transmission of virus by the excimer laser plume.[24] It seems prudcnt then to maintain the same procedures in excimer laser surgery procedures as practiced as in other surgical procedures, e.g., masks, gloves, sterilization of instruments, etc.

Management of Exposures

These recommendations are based on the U.S. Public Health Service Guidelines, published in 2001.[2] Occupational exposures are considered urgent medical concerns so that timely management can be administered.[2] Studies show that postexposure prophylaxis should be initiated as soon as possible, because it is most effective within 24 to 36 hours after exposure. However, even after 24 to 36 hours, it can be considered, because it might still be effective.

If a person has been exposed to a source person already known to be seropositive for HIV or there is a strong likelihood that the source person is HIV infected, then postexposure prophylaxis (PEP) can be initiated as soon as possible, in consultation with physicians with expertise in antiretroviral therapy and HIV transmission. If the source person's HIV status is not known, the use of PEP can be decided on a case-by-case basis. All persons with occupational exposure to HIV should receive follow-up counseling, testing and medical evaluation. For HIV PEP, recommendations include a basic 4-week regimen of drugs, if tolerated, and an expanded regimen for exposures that pose an increased risk for transmission.[2,25]

If the source person is seronegative for HIV, then baseline testing or further follow-up of the exposed health care personnel is not necessary. Otherwise, health care personnel should be tested for HIV within hours of exposure. Serologic testing should be made available to all health care personnel who are concerned that they might have been infected.

For personnel exposed to HBV, it is recommended to initiate the hepatitis B vaccine series to an unvaccinated person, and provide PEP with hepatitis B immune globulin or hepatitis B vaccine in appropriate cases, preferably within 24 hours.[1]

For personnel exposed to HCV, the Public Health Service does not recommend immune globulin or antiviral agents as PEP.[2] However, there have been studies outside the United States that have utilized interferon early in the course of acute hepatitis C to prevent the establishment of chronic hepatitis C.[2,26] In case of percutaneous or mucosal exposure to blood, the CDC recommends that health care institutions have policies to follow-up for HCV infection, which could include testing of the source person for anti-HCV antibodies, and follow-up testing for anti-HCV antibodies of the affected personnel, if the source person is found positive for HCV.[2]

If there is exposure to blood, fluid containing visible blood, or other potentially infectious fluid (not including tears), then the status of the source person should be evaluated for HIV, HBV, and HCV infection as soon as possible.

It is recommended that health care organizations have systems in place for prompt reporting, evaluation, counseling, treatment and follow-up of occupational exposures to bloodborne pathogens.[2] Health care personnel should be educated to report occupational exposures immediately after they occur, because treatment can be most effective if administered as soon as possible after the exposure. Employers subject to OSHA regulations are required to establish exposure control plans that include post-exposure follow-up and to comply with incident reporting requirements.[4]

III. Procedures for protection of the ophthalmologist

Ophthalmologists might be at risk of acquiring HIV, HBV or HCV infection in their professional activities from two major sources: 1) the patient examination, and 2) the setting of surgical intervention.

General Precautions Against Infection – Office

The ophthalmologist personally should follow the same procedures designed to protect office staff and described in Section II. These include handwashing, wearing of gloves where appropriate and taking precautions to prevent injuries caused by needles, scalpels and other sharp instruments. Avoid touching one's own eyelids or contact lenses with the fingers without thorough hand washing.

In the normal ophthalmic office setting, gowns, masks and protective eyewear are usually unnecessary except in situations when splashing with blood or blood-contaminated fluids may be anticipated.

Minor Office Surgical and Diagnostic Procedures

The universal precautions should be observed when performing minor procedures and intravenous fluorescein angiography. In addition to gloves and masks, protective

eyewear should be used if there is a possibility of blood or body fluid splashing.

Surgery

Ophthalmologists are probably most at risk of exposure to HIV and other bloodborne pathogens while performing or assisting in surgery. The following procedures are recommended during surgical procedures:

- Adopt universal precautions for all patients
- Wear gloves when performing all injections
- Handle suture needles with needle holders only
- Develop techniques for safe handling and transfer of sharp instruments
- Follow guidelines given in Section II regarding surgery

IV. Responsibilities Towards Patients with Known or Suspected HIV Infection

Like all physicians, ophthalmologists have a moral and ethical responsibility for providing care to all patients, regardless of whether they are known to be infected with HIV, are known to be seropositive or fall within a "high-risk" group.

Ophthalmologists and ophthalmic medical personnel are at little risk of contracting HIV infection in the course of routine clinical practice. Risks may be further minimized when dealing with those known to be seropositive or suffering from clinical AIDS, but one should remain cognizant of the fact that many seropositive individuals have not been tested. Given the above scenario, bloodborne precautions are warranted for all appropriate patients.

Conclusion

The risk of contracting HIV infection in the ophthalmic healthcare setting is estimated to be extremely remote. Although HIV has been isolated from tears and other ocular fluids, the titer is extremely low and is considered by many authorities to be below an inoculating dose. To date, there is no evidence that the infection has been acquired from contact with tears. However, it must be remembered that these precautions will be effective against other more infectious agents than may be encountered in patients with HIV infection. These OSHA and CDC guidelines are intended to help protect the public and ophthalmic medical personnel, and minimize transmission of bloodborne pathogens and surface infectious agents.

Additional Resources:

Further information on the CDC guidelines can be obtained by viewing the CDC website for Division of Healthcare Promotion http://www.cdc.gov/ncidod/hip/.

Further details on the OSHA regulations including regulations governing HIV and HBV research laboratories and production facilities can be obtained by viewing the OSHA website (http://www.osha.gov/) or ordering publications online (http://www.osha-slc.gov/OshDoc/Additional.html)

Occupational Safety and Health Bloodborne Infectious Disease
www.cdc.gov/niosh/bbppg.html

State needle safety legistation: www.cdc.gov/niosh/ndl-law.html

Exposure management resources:

National Clinicians' Postexposure Prophylaxis Hotline (PEPline)
1-888-448-4911

Needlestick! www.needlestick.mednet.ucla.edu

Hepatitis hotline 1-888-443-7232

Reporting to CDC: Occupationally acquired HIV infections and failures of PEP
1-800-893-0485

HIV/AIDS treatment information service
www.hivatis.org

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Fuse Replacement

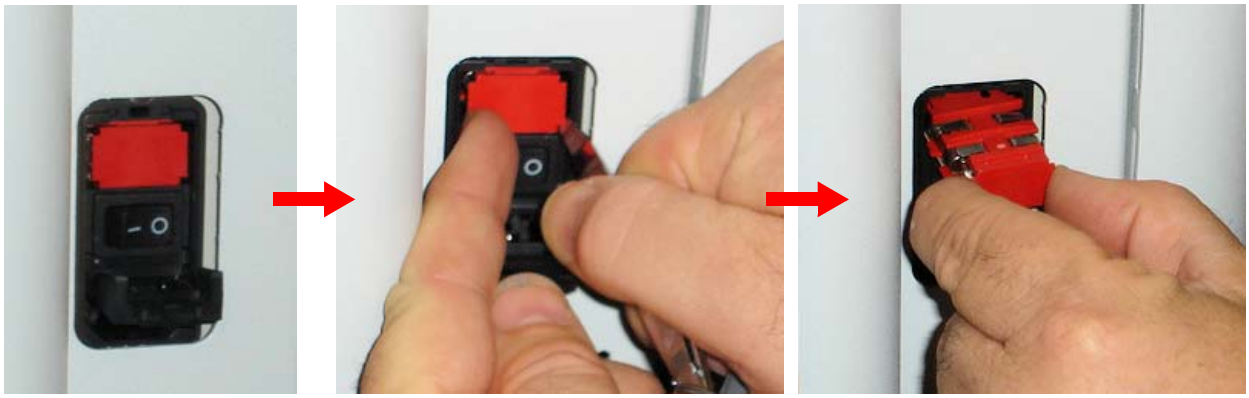
Locate the power entry module on the lower right side of the rear of the cart. Make sure to remove the power cord before proceeding any further. (See Figure 70.)

Figure 70 Power Entry Module

Using a flat blade screwdriver, gently pry open the cover of the fuse holder at the top of the power entry module. (See Figure 71.)

Figure 71 Opening the fuse holder cover

Remove the fuse holder. (See Figure 72.)



Cover open | Gently pry at edges to start removal | Finish removal with fingers

Figure 72 Removing the fuse holder

Remove the blown fuse from the fuse holder and replace it with a new fuse of same type and rating. (See Figure 73.)

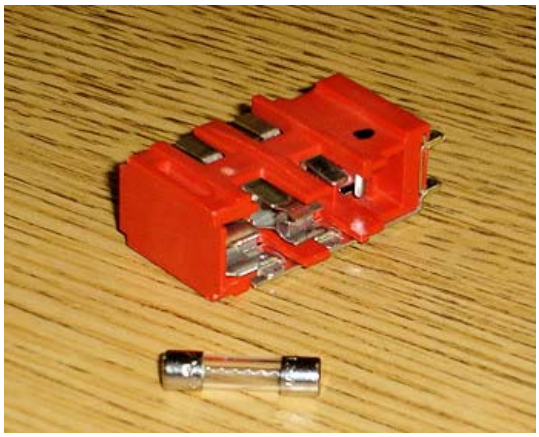


Figure 73 Blown fuse removed

☞ **Fuse Type: T 3A / 250V**

CAUTION: For continued protection against risk of fire, replace only with same type and rating fuse.

Replacement fuses are available from Clarity Customer Service. Call (800) 215-6005 toll-free in the US. Outside the US, contact your distributor. The part number for the fuse is 20-000097. (See complete Technical Support Contact Information on page 114.)

When you have replaced the blown fuse, reinsert the fuse holder fully and close the cover.

Replace Illumination Lamp

WARNING: Appropriately power down and unplug the unit and allow the illumination lamp to cool before replacing it.

The illumination light bulb located in the EO box will need periodic replacement. It is a 12 volt, 75 watt halogen bulb, industry type EKE. Replacement bulbs are available from Clarity Customer Service. Call (800) 215-6005 toll-free in the US and ask for replacement part number 02-04-501. (See complete Technical Support Contact Information on page 114.)

Follow these steps to replace the illumination lamp found in the EO box:

1. If it is not already turned off, turn off the instrument according to the instructions found under Turning Off the RetCam Shuttle on page 31.
2. Disconnect the main power cord from the wall.
3. Unplug the fiber optic cable from the front of the EO box.

4. Remove the two screws from the lamp assembly drawer, the smaller panel with the black handle on the front of the EO box.

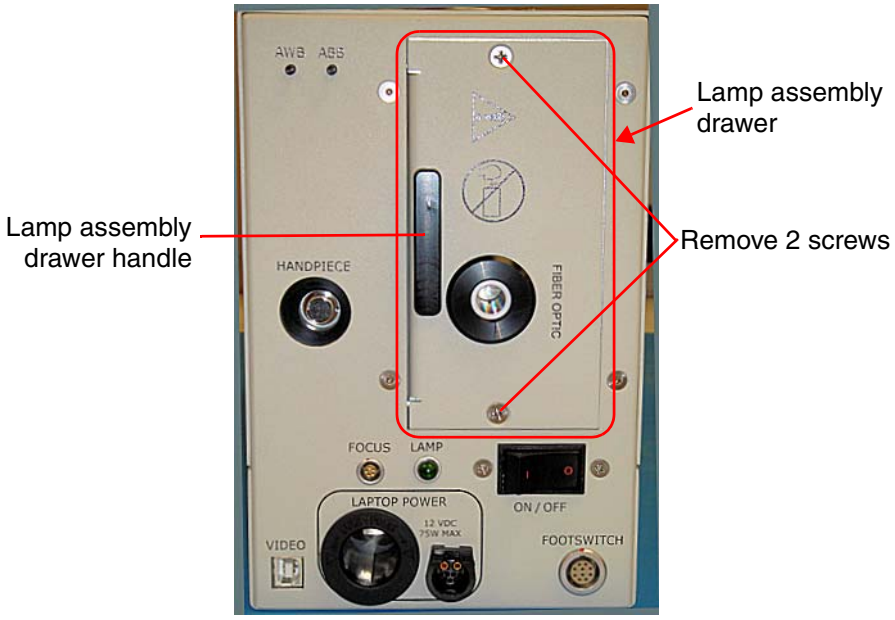


Figure 74 Front panel of the EO box showing the lamp assembly drawer

5. Grip the handle on the lamp assembly drawer. Pull the drawer out slowly from the EO box. Stop when the light bulb is fully exposed.

6. Just above the socket and rising from the rear of the illumination lamp is a thick gray wire, the “lamp ejector” indicated in the picture below. Be prepared to grab or catch the illumination lamp unit as you gently rotate this wire toward you (rotate it toward the right from the front, or counterclockwise), which ejects the lamp. Remove the old illumination lamp.

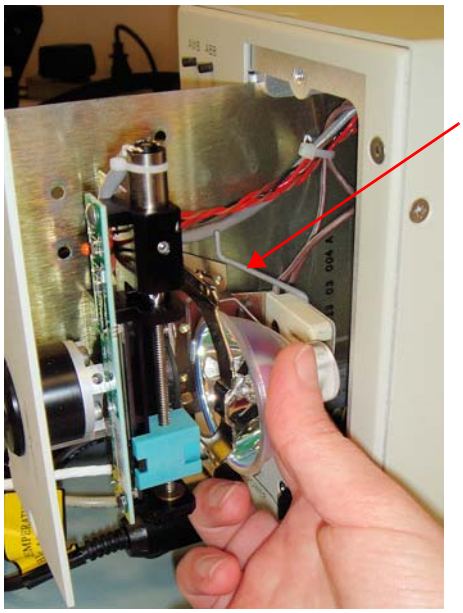


Figure 75 Removing the illumination lamp

CAUTION: Only touch the exterior surface of the illumination lamp. Do not touch the bulb, which is located in the center of the reflector, nor the inner (concave) surface of the reflector. Skin oils will adhere to the bulb and reflector, which reduces the cooling efficiency of the bulb and thereby creates a hot-spot leading to premature burnout. Handle by the outside of the lamp only, as shown.

7. **Holding the new lamp only on the outside,** as shown, replace it in the assembly, aligning the two pins in the rear with the corresponding tracks in the socket and pushing it gently and evenly into place.
8. Check the position of the new bulb to make sure that the reflector of the bulb is located in the center of the lamp socket’s opening.
9. Push the lamp assembly drawer back into the EO box carefully. Use caution to avoid pinching wires in the area.
10. Replace the two screws on the small front panel.

Key Validation

Note: New RetCam Shuttle systems ship with their license key already registered and validated. However, significant changes to the system

hardware or a re-load of the system software for any reason (including software upgrade) may require you to perform the key validation process as described below. Key validation requires that you get a license key from Clarity to use the revamped system, and you cannot request this key until after installation is complete. Since it may take up to two (2) business days to obtain a license key after submitting a request, we recommend that you affect system or software upgrades when you can manage two business days without use of the system.

☞ **Note: To ensure the preservation of your patient data and images, we strongly recommend that you perform a complete backup of the system's images before you begin any software installation.**

When key validation is necessary, the Key Validation dialog appears when you start the system (and each time thereafter until you complete this step), before the Site Awareness dialog.

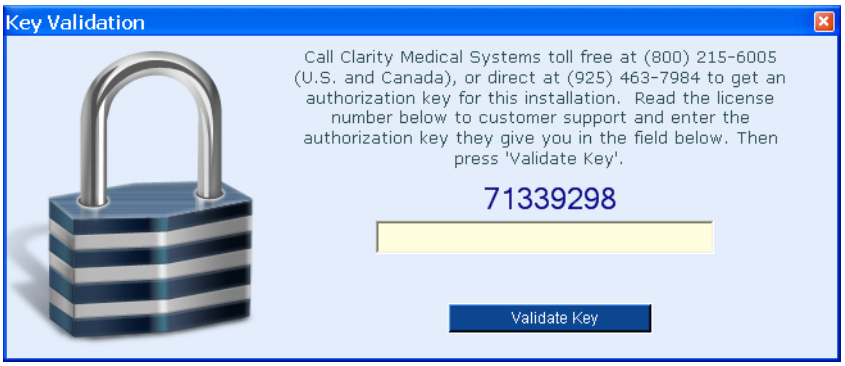

Key Validation
Call Clarity Medical Systems toll free at (800) 215-6005 (U.S. and Canada), or direct at (925) 463-7984 to get an authorization key for this installation. Read the license number below to customer support and enter the authorization key they give you in the field below. Then press 'Validate Key'.
71339298
Validate Key

Figure 76 Key Validation dialog

Follow the instructions on screen: Call Clarity and provide to the customer support representative the large license number in the dialog (71339298 in the example above), which is unique for your system. You will be provided in turn a unique authorization key.

Tip: You may also send the license number via email to **service@retcam.com** and receive the authorization key by return email.

You must enter the authorization key in the field and click **Validate Key** to access the system software. If you call, to make sure you enter the number correctly, we recommend you do not hang up until the number is accepted.

Technical Support

How to Get Support

The User Manual and Service Manual have been written to answer the majority of questions that arise with the product. Please consult these manuals before calling for service.

The in-house technical staff of Clarity Medical Systems, Inc. (CMS) is dedicated to helping our users with any specific problems and questions you may have with the RetCam Shuttle. Please have your serial number ready and include the serial number on all correspondence. The serial number is located on a sticker affixed to the base of the cart at the back just above the power cord connection.

Please be as specific and give as much information as possible. If you encounter a system malfunction of any kind, please record the exact steps taken leading to the failure, so that our staff can replicate the problem.

Technical Support Contact Information

Customers outside the US, please contact your distributor for technical support.

In the US, you have the following options:

Telephone

Toll-free: (800) 215-6005

Fax: (925) 251-0078

Telephone support is typically available between the hours of 9am and 5pm Pacific Time.

Send correspondence to:

Clarity Medical Systems, Inc.

5775 West Las Positas Blvd.

Pleasanton, CA 94588

USA

Email

service@retcam.com

Our US technical support staff will respond to your questions as soon as a staff member is available. In most cases, you should receive an answer within 48 hours. Complex questions that require testing or special research may take longer.

☞ **Note: Questions about products no longer under warranty and questions other than to explain ordinary use of the product may incur service charges. Please ask for an hourly quotation before incurring charges.**

Returning Parts for Repair

If after consulting with CMS technical support to CMS for repair or replacement, a Return Materials Authorization Number (RMA #) must be issued by CMS. The RMA number must be noted on the return shipping documents so that the disposition of the part is known when it is received at CMS offices.

Should your CMS product prove defective during the period covered by warranty, please call, fax or write to CMS at the numbers and address listed above for an RMA number. Each separate part must be securely packaged and returned to CMS in its original shipping container or an equivalent. Please clearly mark the outside of each returned package with the RMA number.

CMS will, at its option, repair or replace any defective or damaged part or component. Determination regarding whether service and repairs are completed at the customer site or the defective or damaged part(s) are returned to CMS‘s facilities for repair shall be made by CMS on a case by case basis. Costs incurred to complete service or repair, including parts, labor, travel and shipping, not covered by warranty will be billed to the customer upon successful completion of the service or repair. For repairs not under warranty, a purchase order (PO) will be required to cover the evaluation.

Service Information

Service information is available separately in the RetCam Shuttle Service Manual.

RetCam Shuttle components are typically return-to-factory components and can be repaired by only Clarity personnel and/or our qualified distributors. The Service Manual contains information on user-replaceable parts and/or instructions to remove components for return for factory repair.

9 Specifications

Hardware

Physical

- 19” (483 mm) wide x 19”(483 mm) deep x 34”(864 mm) high
- 75 mm front swivel casters with brakes
- 75 mm rear casters
- Approximately 65 lbs. (30 Kg)
- Low center of gravity
- Temperature range: 59º F to 95º F or 15º C to 35º C
- Humidity range: non-condensing 10% to 95%

Electrical

- Power consumption: 250 VA maximum
- Input Power: 100-240V~, 50/60 Hz
- Detachable hospital grade power cord

Cart Features

- Two storage containers for lenses and supplies
- Internal handpiece holster
- Secondary work surface
- Tri-function footswitch
- Dual 5" front locking casters
- Extendable handle for system transport

Custom Light Source

- Adjustable intensity iris
- Automatic black and white balance functions
- Lemo focus motor connector
- Custom fiber optic
- Automatic fan speed controller
- Easy-access bulb replacement

Handheld Imager

- 3-chip RGB CCD
- Full 24-bit color

- Full-resolution capture from video
- Quick-change front lens piece, 5 options

Notebook Computer

- Intel® Pentium® M 2.1 GHz processor
- 1GB Random Access Memory
- 80 GB hard drive
- DVD/R/RW drive
- 3 USB connections
- Audio
- 10/100 Ethernet Adapter
- Intel 128MB Video Adapter

Software

- MS Windows® XP SP2 operating system
- Proprietary image acquisition, storage and processing
- Live color image display
- Integrated patient database
- Still and video capture modes
- Review functions
- Compare functions
- Transfer / backup functions
- Data export as XML, CSV, or TXT with automatic patient organization
- Image export as bitmap, jpeg, or png
- Image annotation

Environmental Conditions

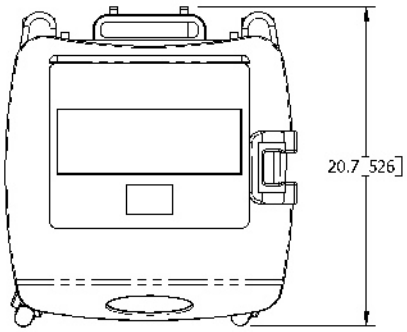
The system as delivered is intended for use indoors, at normal room temperatures, upright, on a level surface, with the brakes applied to the front casters.

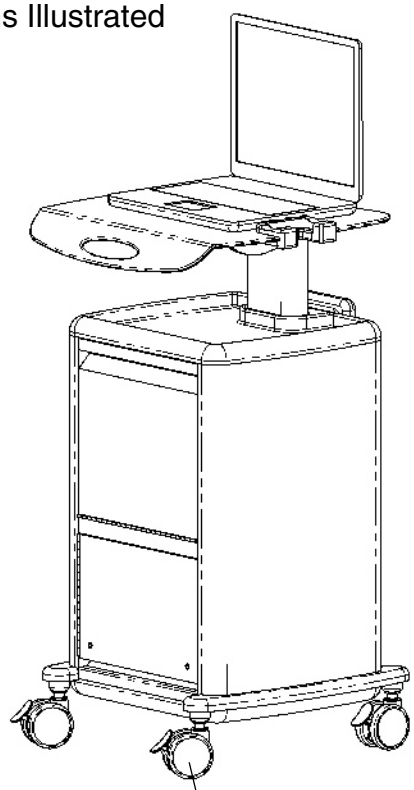
Condition	Operating	Storage and Transport
Temperature	59º to 95º F (15º to 35º C)	-4º to 122º F (-20º to 50º C)
Relative Humidity	10% to 95% non-condensing	10% to 85% non-condensing
Atmospheric Pressure	20.7 to 31.3 inches Hg (70 to 106 kPa)	14.7 to 31.3 inches Hg (50 to 106 kPa)
Altitude	-1255 to 9882 feet (-382 to 3012 meters)	-1255 to 18288 feet (-382 to 5574 meters)

☞ **Note: Specifications subject to change without notice.**

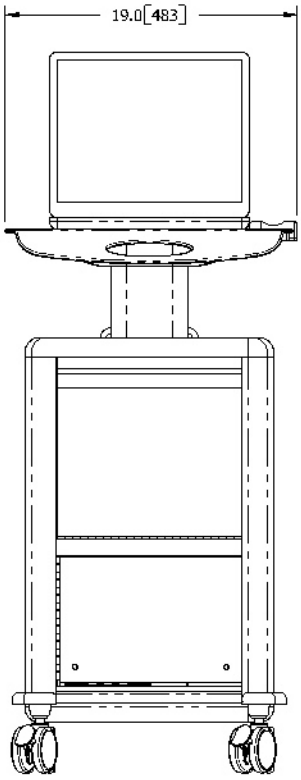
RetCam Shuttle Dimensions Illustrated

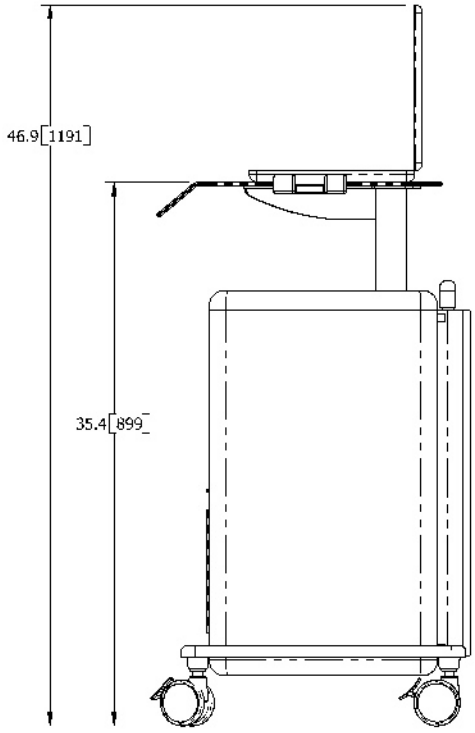
Dimensions in [brackets] are millimeters





All casters swivel under base





10 License Agreements

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